DOTS- sure cure for TB.

Managing the Revised National Tuberculosis Control Programme in your area

A Training Course

Modules 1- 4

- **Course Introduction**
- **Ensuring Identification of Tuberculosis Suspects**
- **Supporting Laboratory Services**
- **Administering Treatment**

सत्यमेव जयते

Central TB Division
Directorate General of Health Services, Ministry of Health and Family Welfare
Nirman Bhavan, New Delhi 110011

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MODULE 1: COURSE INTRODUCTION

PURPOSE OF THE TRAINING COURSE

Tuberculosis (TB) remains a major public health problem in India. Every year approximately 18 lakh people develop TB and about 4 lakh die from it. India accounts for one fifth of global incidence of TB and tops the list of 22 high TB burden countries. Unless sustained and appropriate action is taken, approximately 20 lakh people in India are estimated to die of TB in next five years.

TB kills more adults in India than any other infectious disease.

In India, EVERY DAY:

- more than 5000 develop TB disease
- more than 1000 people die of TB (i.e. 1 death every 11/2 minutes)

Despite the existence of a National Tuberculosis Programme since 1962, there was little impact on the TB burden till 1992. This programme could not achieve the objectives because of low priority, managerial weaknesses, over dependence on X-rays for diagnosis and inadequate funding. Incomplete treatment was the norm rather than exception due to low rates of treatment adherence and lack of supervision.

On the recommendations of an expert committee, a revised strategy to control TB was pilot-tested in 1993 in a population of 23.5 lakh and thereafter increased in phased manner. A full-fledged programme was started in 1997 and rapidly expanded with excellent results. This Revised National Tuberculosis Control Programme (RNTCP) uses the DOTS (Directly Observed Treatment, Short-course chemotherapy) strategy, which is based on results of tuberculosis research done in India.

The "DOTS strategy" is the globally accepted standard for diagnosis and treatment of tuberculosis.

A major organizational change in RNTCP is the creation of a sub-district level. The sub-district will consist of a designated Medical Officer-Tuberculosis Control (MO-TC) who does tuberculosis work in addition to his/her other responsibilities, as well as two full-time supervisory staff for tuberculosis work—a Senior Treatment Supervisor (STS) and a Senior Tuberculosis Laboratory Supervisor (STLS). The State, District and Sub-district staffs are responsible for organizing, implementing and supervising RNTCP, and the success of the programme depends on them.

During the course of this training you will learn the objectives, strategies, diagnosis, classifications of disease, treatment categorization, methods of supervision, and recording and reporting in RNTCP.

This course draws on two sets of WHO training modules: Managing Tuberculosis at District Level and Managing Tuberculosis at National Level. This course provides training relevant to implementing RNTCP at the state, district and sub-district levels. Staff who can benefit from this course include state-level staff (State TB Officer, Director and staff of State TB Demonstration and Training Centre), district-level staff (District TB Officer, Medical Officer of the DTC), and the designated Medical Officer (MO TC) of the sub-district. Modules 1– 4 of the course are very relevant for other Medical Officers of all sectors.

At the end of this course, participants will be able to do the following tasks:

- train MOs and health workers to correctly identify patients who should be investigated for tuberculosis at nearest Designated Microscopy Centres
- monitor the maintenance of the Tuberculosis Laboratory Register
- monitor documentation related to sputum microscopy examinations
- classify and categorize patients for treatment correctly
- complete TB Treatment Cards of patients
- ensure proper administration of drugs through directly observed treatment (DOT)
- identify, train and supervise others who give directly observed treatment (peripheral health workers, community volunteers, etc.)
- provide health education to patients and their families and train MOs and health workers to do the same
- monitor the registration of patients in the Tuberculosis Register
- verify that correct number of sputum specimens have been examined at stipulated intervals and the results have been recorded in the Tuberculosis Register
- regularly review Tuberculosis Treatment Cards to assess treatment outcomes and to verify that the treatment outcomes have been recorded correctly in the Tuberculosis Register
- complete and submit the monthly PHI reports in the standardized format

- complete and submit the quarterly reports on case-finding, sputum conversion, treatment outcomes and programme management
- ensure maintenance of Binocular Microscope, adequate supply of drugs, printed materials and laboratory consumables
- conduct regular supervisory visits and provide feedback for corrective actions
- make active efforts to involve other health service providers of the public as well as the private sector
- evaluate the performance of the tuberculosis programme in the area

TB can be controlled only with EFFECTIVE SUPERVISION and GOOD PROGRAMME MANAGEMENT

EXTENT OF THE TUBERCULOSIS PROBLEM

Tuberculosis is an infectious disease caused by Mycobacterium tuberculosis and, less commonly, by other organisms of the 'tuberculosis complex'. Globally, it is estimated that 18 lakh people die from TB each year—the majority of them in developing countries. The annual incidence of new cases of all forms of TB (pulmonary and extra-pulmonary) worldwide is estimated to be approximately 88 lakhs, of which about 95% occur in developing countries. Many TB cases in developing countries remain undetected.

In India, more than 40% of population is infected with TB bacilli.

Tuberculosis is a barrier to socio-economic development and costs the country more than Rs.12,000 crore per year. The greatest burden of tuberculosis incidence and mortality in India is in adults aged 15 to 60 years, which include the most productive members of society. TB kills more women than all causes of maternal mortality.

Every year due to TB:

- More than 17 crore work-days are lost
- nearly 3 lakh school children dropout from the schools
- more than 1 lakh women are rejected by their families

One of the key epidemiological indicators of the tuberculosis situation in a community is the annual risk of tuberculosis infection (ARTI). It represents the proportion of population that gets newly infected (or reinfected) with tubercle bacilli over the course of

one year. Currently the average ARTI in the country as a whole is estimated to be 1.5%. It has been estimated that for every one percent annual risk of tuberculosis infection, there are about 50 new pulmonary sputum smear-positive (NSP) cases per 100,000 population per year. Out of all new TB cases 85-90% are Pulmonary and 10-15% are Extrapulmonary. Of the New Pulmonary TB cases 50% are expected to be sputum positive. This means that, with an ARTI of 1.5%, there will be 75 new smear-positive cases, 75 new smear-negative cases, 38 re-treatment cases, and 15 extra-pulmonary cases, totaling to 203 cases per lakh population per year. The ARTI varies for different zones of the country, which is given in Module 9.

While in the past forty-five years there has been a tremendous decrease in tuberculosis cases in developed countries, there has been an increase in the number of tuberculosis cases in developing countries. This is due to the failure to cure a high proportion of sputum smear-positive cases, population growth, HIV-epidemic and other factors (socio-economic, etc).

Under the TB Control programme, priority is given to the smear-positive cases. Every smear-positive person, if left untreated, has the potential to **infect 10-15 persons per year**, thereby increasing the pool of infected persons. In a well performing Programme, cure rate of more than 90% can be achieved.

A poorly managed TB control programme can worsen the epidemiological situation of TB in a community.

Childhood TB is a reflection of the prevalence of sputum smear-positive pulmonary tuberculosis (PTB) and the extent of transmission of infection in the community. It had hitherto been accorded low priority since it is less infectious. The serious forms of TB are more common in children and they are more likely to die if not treated properly.

Many patients who do not receive directly observed treatment (DOT) stop taking their anti-TB drugs. Studies show that at least one-third of the patients do not take medicines regularly. Such patients may become resistant to the drugs they have taken and may suffer from Multi Drug Resistant TB (MDR-TB). These patients may then infect other people with drug-resistant bacilli. MDR-TB is a specific form of drug resistant TB due to bacilli resistant to at least isoniazid and rifampicin, with or without resistance to other anti-TB drugs. Drug resistance arises due to improper use of anti-tuberculosis drugs during treatment. Drug resistance arises in areas with poor TB control programmes, which is often a reflection of lack or improper implementation of DOTS in such areas.

Globally, the HIV epidemic is worsening the TB situation, increasing the number of tuberculosis cases and accelerating the spread of the disease. HIV increases a person's susceptibility to TB infection. HIV is now considered the most powerful risk

factor for the progression of TB infection to disease. One third of the world's AIDS cases are suffering from TB. There are 51 lakh people living with HIV in India (2004 estimate) of whom 50-60% will develop TB in their lifetime, compared to 10% of HIV negative persons infected with TB.

OBJECTIVES OF THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME (RNTCP)

In developing countries, such as India, the fight against tuberculosis can be successfully carried out only within the setting of a National Tuberculosis Control Programme. The programme is integrated with the country's general health services.

The goal of RNTCP is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem. The goal is achieved through the objectives.

The objectives of RNTCP are

- To achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear-positive) cases, and
- To achieve and maintain detection of at least 70% of such cases in the population

However, the target for case detection should only be attempted once the cure rate of 85% is achieved among new sputum smear-positive patients already detected.

The results of the pilot tests of RNTCP in 1993 showed that diagnostic practices improved significantly with effective use of quality sputum microscopy, and cure rates doubled compared to those achieved by the previous programme. By the end of March 2005, RNTCP has been extended to 564 districts in 31 States and Union Territories to cover a population of more than 1 billion (100 crores, about 90% of the population of the country) and whole of the country will be covered by the end of 2005.

The Objectives of RNTCP are to achieve and maintain at least 85% cure rate of new sputum smear-positive patients and to achieve and maintain detection of at least 70% of such cases in the population.

The only effective means by which 85% cure rate or more has been shown to be achievable on a programme basis is by application of the DOTS strategy. It should be noted that the principles of diagnosis of TB by sputum microscopy, ambulatory treatment, and direct observation of treatment were first established in India at the Tuberculosis Research Centre, Chennai and the National TB Institute, Bangalore, in the1950s and 1960s.

DOTS is a systematic strategy which has 5 components. These are as follows:

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of good quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

- **Political and administrative commitment:** Since tuberculosis can be cured and the epidemic reversed, it warrants the topmost priority, which has been accorded by the Government of India. This priority must be continued and expanded at state, district, and local levels.

- **Good quality diagnosis:** Case detection is done primarily by sputum microscopy among chest symptomatic patients attending health facilities. This policy allows effective diagnosis in the periphery and appropriate prioritization of efforts.

- **Good quality drugs:** An uninterrupted supply of good quality anti-TB drugs must be available. In RNTCP, a box of medications for the entire course of treatment is earmarked for every patient registered, ensuring the availability of the full course of treatment to the patient the moment he/she is diagnosed to be suffering from tuberculosis. Hence, in **RNTCP** the treatment never fails on account of non-availability of medicines.

- **Short-course chemotherapy given in a programme of direct observation:** RNTCP uses the best anti-TB medications available but unless patients adhere to treatment, it will fail. This is why the heart of the DOTS programme is "directly observed treatment (DOT)" in which a health worker or another trained person who is not a family member, watches the patient swallow the anti-TB medicines in his/her presence.

However, directly observed treatment (DOT) is not just supervised swallowing but a service to the patient. It helps to develop a human bond between the patients and the treatment observer, which increases the probability of the patient completing treatment. With short-course chemotherapy it is easier to prevent drug resistance by using directly observed treatment, and achieve high cure rates.

DOTS strategy is very important for HIV infected TB patients to promote adherence to therapy which cures TB and improves their quality of life. **HIV epidemic can lead to a threefold increase of TB cases**

- **Systematic monitoring and accountability:** There are two means of monitoring the success of treatment. First, sputum is examined during the course of treatment to monitor the progress and cure of patients. Second, a revised recording and reporting system rigorously monitors and evaluates the outcome of every patient treated at the different levels of the health system, and if any area is not achieving 90% sputum conversion rate at the end of 3 months and 85% cure rate, supervision is intensified. For effective programme implementation, having well-trained and motivated staff is essential.

RNTCP shifts the responsibility for cure from the patient to the health system.

When cure rates are high, health facilities will attract more patients due to the good results obtained in the cases already treated. As one Programme Manager of a successful RNTCP site in India said, '**Every cured patient is a pamphlet**'.

Remember: Achieve the cure rate before attempting to increase the case detection.

STRUCTURE OF THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

The structure of RNTCP comprises of five levels, as follows:

1 National
2 State
3 District
4 Sub-district
5 Peripheral health institutions

A major organizational change is the creation of a sub-district level – the tuberculosis unit (TU) for the systematic monitoring and supervision of diagnostic and treatment aspects of the programme. State TB Control Societies (STCSs) and District Tuberculosis Control Societies (DTCSs) have been formed to give more ownership to the states and districts. Hence, states will assume direct responsibility for monitoring and supervision of the work of the District TB Control Societies (DTCSs) in the state for implementation of RNTCP. States will prepare and ensure the implementation of an action plan for the improvement of RNTCP on an annual basis. Establishment of societies provides greater discretion and enhanced responsibility to states/districts over financial matters.

National level (Central TB Division)

The Central TB Division (CTD) is a part of the Ministry of Health and Family Welfare (MoHFW), and is responsible for tuberculosis control in the whole country. A National Programme Manager, the Deputy Director General TB (DDG TB), is in charge of the tuberculosis programme for the entire country. CTD plans, supervises, monitors and evaluates programme activities throughout the country.

State level

With the rapid expansion of the programme, MoHFW has re-structured and strengthened the functions of the State TB Control Society (STCS). The States have increased ownership and accountability for implementation. Capacity building and de-centralization are taking place in the technical, financial as well as logistic aspects of the programme. The States, via the STCSs, are now directly responsible for monitoring and supervising the work of District TB Control Societies (DTCSs).

At the State level, the State Tuberculosis Officer (STO) is responsible for planning, training, supervising and monitoring the programme in their respective states as per the guidelines of the STCS. The STO based at the State TB Cell is administratively answerable to the State Government and technically follows the instructions of the CTD, and coordinates with CTD and the districts for executing the duties mentioned above. There should be a full-time STO trained in RNTCP for each state. In major states of the country, a state TB Training and Demonstration Centre (STDC) supports the state TB cell by providing training, supervision co-ordination, monitoring and technical functions.

District level

The district is the key level for the management of primary health care services. The district level (or municipal corporation level) performs functions similar to those of the state level in its respective area. The Chief District Health Officer or an equivalent functionary in the district is responsible for all medical and public health activities including control of TB.

The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district. In RNTCP, the primary role of the DTC has shifted from a clinical one to a managerial one. The District TB Officer (DTO) at the DTC has the overall responsibility of physical and financial management of RNTCP at the district level as per the guidelines of the DTCS. The DTO is also responsible for involvement of other sectors in RNTCP and is assisted by an MO, Statistical Assistant and other paramedical staff. For each district, there should be a full-time DTO, who is trained in RNTCP at a central level institution.

Sub-district level (Tuberculosis Unit level)

A team, comprising a specifically designated Medical Officer – TB Control (MO-TC), Senior Treatment Supervisor (STS) and Senior Tuberculosis Laboratory Supervisor (STLS), is based in a Community Health Centre (CHC), Taluk Hospital (TH) or Block Primary Health Centre (BPHC). The team of STS and STLS at the Tuberculosis Unit level (TU level) are under the administrative supervision of the DTO / MO-TC.

The TU covers a population of approximately 5 Lakhs (2.5 Lakhs in tribal, desert, remote and hilly regions). The TU will have one Microscopy Centre for every 1 Lakh population (0.5 Lakh in tribal, desert, remote and hilly regions) referred to as the Designated Microscopy Centre (DMC). DMCs are also provided in Medical Colleges, Corporate hospitals, ESI, Railways, NGOs, private hospitals, etc, depending upon requirements. The TU is responsible for accurate maintenance of the Tuberculosis Register and timely submission of quarterly reports to the district level.

The TU is the nodal point for TB control activities in the sub-district. MOTC at the TU has the overall responsibility of management of RNTCP at the sub-district level and is assisted by the STS and STLS. MO-TC is also responsible for involvement of other sectors in RNTCP. The MO-TC is trained in RNTCP at a state level institution, preferably State TB Training and Demonstration Centre (STDC).

The MO-TC at the TU is responsible for organizing sputum smear examination at all DMCs of the sub-district, carrying out treatment categorization of diagnosed patients (and supporting other MOs of the sub-district to do the same), and ensuring that DOT is taking place as per guidelines at all DOT centres. He should ensure a regular supply of drugs and other logistics and ensure their uninterrupted availability in all peripheral health institutions in the sub-district. MOTC is responsible for updating records and preparing quarterly reports on case finding, sputum conversion, results of treatment outcome and programme management of the corresponding TU.

Key functions of the Tuberculosis Unit team are to

- **Maintain the Tuberculosis Register**
- **Organize and ensure effective diagnosis and direct observation of treatment**
- **Prepare quarterly reports on case finding, sputum conversion, results of treatment, and programme management**
- **Ensure adequate supply of drugs, reagents and logistics regularly**
- **Involvement of other sectors in RNTCP**
- **Ensure effective IEC activities**

Peripheral Health Institutions (PHIs)

At this level are the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics / hospitals (including other health facilities) within the district. Some of these PHIs will also be DMCs.

Main responsibilities of the MO at the PHIs (including those at DMCs)
Refer tuberculosis suspects or send their sputum specimens to DMC for examination.

- Carry out treatment categorization of diagnosed patients; give health education to them; identify DOT providers1 for them (in consultation with the concerned workers as well as the patients) and start DOT within 7 days of diagnosis.
- Trace patients who interrupt treatment and bring them back to treatment
- Maintain up-to-date Tuberculosis Treatment Cards and records and make them available to supervisory staff when they visit the health facilities.
- Monitor and facilitate follow-up sputum smear examinations.
- Identify and investigate contacts.
- Mention treatment outcomes in the treatment cards.
- Identify and train DOT provider as and when needed, update list of DOT providers under intimation to MO-TC.
- Submit monthly report on programme implementation and logistics to the TU.
- Supervise and monitor DOT services in their jurisdiction
- MOs of DMC are also responsible for supervision and monitoring the microscopy activities of their institution.

The central state, district and sub district levels must carry out their responsibilities to achieve the objectives of RNTCP.

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1 Health worker or community volunteer, other than a family member, who administers DOT, and is accessible and acceptable to the patient and accountable to the health system

UNIQUE features of RNTCP

- **District TB Control society (DTCS)**
- **Sub-district level supervisory staff for microscopy and treatment services (MOTC, STS and STLS) – provision of two-wheelers for supervision by STS/STLS**
- **Modular training for all staff**
- **Patient-wise treatment boxes (PWB)**
- **Robust recording and reporting system**
- **Quarterly review of performance at all levels**

POINTS TO REMEMBER

- TB is the **number one killer** of adults among all infectious diseases, in India.
- India tops the list of 22 high TB burden countries in terms of incidence of TB.
- **DOTS** is the best strategy to cut the **chain of transmission** in the community
- The Objectives of RNTCP are **to achieve and maintain a cure rate of at least 85% among newly detected sputum smear-positive cases and to achieve and maintain detection of at least 70% of such cases in the population**.
- The TB Patient is the **VIP** of the programme and the responsibility of cure has been shifted from the **patient to the health system.**
- **Tuberculosis Unit** covers a population of 5 lakhs.
- There is a DMC for every 1 lakh of population.
- Urgent action is warranted to avert worsening of the TB epidemic due to MDR-TB and HIV-TB.
- A **well managed** TB control programme will **save many lives** and reduce the economic burden.

STRUCTURE OF EXERCISES OF THE TRAINING MODULES

All modules have **individual** and/or **group exercises** that are designed to check if you have learnt the skills that were taught. After you complete an exercise, a facilitator will assess and comment on your work.

Before each **individual exercise**, you will see a picture like this:

For the **group exercises**, you will be asked to work with other participants to discuss answers to a given situation or to participate in a role play. A facilitator will lead the small group discussions and observe and comment on each role play. Before each **group exercise**, you will see a picture like this:

For the **exercise workbooks**, you will see a picture like this:

EXERCISE 1

This exercise will give you an opportunity to know what you have learnt in this module. Complete the questions below and discuss with your facilitator.

1. What are the five components of DOTS?

2. What are the objectives of RNTCP?

3. What is the population covered by a Tuberculosis Unit (TU)?

4. What is the population covered by a Designated Microscopy Centre (DMC)?

DEFINITIONS: THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Case definitions	Types of cases	Treatment outcomes
Pulmonary Tuberculosis, Smear-Positive TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB. Or: TB in a patient with one sputum smear examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO. Or: TB in a patient with one sputum smear specimen positive for AFB and culture positive for M.tuberculosis. **Pulmonary tuberculosis, Smear-negative** TB in a patient with symptoms suggestive of TB with at least 3 sputum smear examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO followed by a decision to treat the patient with a full course of anti-tuberculosis therapy. Or: Diagnosis based on positive culture but negative AFB sputum smear examinations. **Extra Pulmonary tuberculosis** TB of any organ other than the lungs, such as the pleura (TB pleurisy), lymph nodes, intestines, genitourinary tract, skin, joints and bones, meninges of the brain, etc. Diagnosis should be based on culture-positive specimen from the extra-pulmonary site, histological, radiological, or strong clinical evidence consistent with active extra pulmonary TB followed by decision of the treating MO to treat with a full course of anti-TB therapy. Pleurisy is classified as extra pulmonary TB. A patient diagnosed with both sputum smear positive pulmonary and extra pulmonary TB should be classified as pulmonary TB.	**New** A TB patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month. **Relapse** A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear positive. **Transferred in** A TB patient who has been received for treatment into a Tuberculosis Unit, after starting treatment in another unit where s/he has been registered. **Treatment after default** A TB patient who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear positive. **Failure** Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment. **Chronic** A TB patient who remains smear positive after completing a re-treatment regimen. **Others** TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.	**Cured** Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on two occasions, one of which was at the end of treatment **Treatment completed** Sputum smear-positive patient who has completed treatment, with negative smears at the end of the intensive phase but none at the end of treatment. Or: Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment. Or: Extra-pulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment. **Died** Patient who died during the course of treatment regardless of cause **Failure** Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment. **Defaulted** A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment. **Transferred out** A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment result (outcome) is not known.

Module 2:
Ensuring Identification of Tuberculosis Suspects

MODULE 2: ENSURING IDENTIFICATION OF TUBERCULOSIS SUSPECTS

INTRODUCTION

Tuberculosis (TB) affects the lungs in more than 85% of cases. This form of the disease is called pulmonary tuberculosis.

Pulmonary tuberculosis is an infectious disease. People living with or coming in close contact with a patient who has undiagnosed and untreated infectious tuberculosis (in particular, smear-positive) have the risk of getting infected. Therefore, it is very important to identify suspects who have symptoms of tuberculosis early in the course of the disease and ensure their treatment.

The main tools for diagnosing pulmonary TB are sputum smear microscopy, chest X-ray, and culture of Mycobacterium tuberculosis bacilli.

- Sputum microscopy is easy to perform at the peripheral laboratories, not expensive and specific with low inter and intra reader variation. Therefore, this is the key diagnostic tool used for case detection in RNTCP.
- X-ray as a diagnostic tool is sensitive but less specific with large inter and intra reader variations.
- Culture of Mycobacterium tuberculosis bacilli is very sensitive and specific but is expensive as it requires a specialized laboratory set-up and results are available only after several weeks.

Sputum smear microscopy is the primary tool for diagnosing TB as it is more specific and has less inter-reader variability than X-ray.

Tuberculosis may also affect organs other than the lungs. This form of the disease is called extra-pulmonary tuberculosis. Methods for the diagnosis of extra-pulmonary cases depend on the system that is affected.

Sputum Microscopy

- Simple not expensive, requires minimum training
- Specific with low inter-reader variation

- Can be used for diagnosis, monitoring and defining cure
- Feasible at peripheral health institutions
- Correlates with infectivity in undiagnosed pulmonary TB cases

X-ray

- Supportive to microscopy
- High inter-reader variation
- No shadow is typical of TB
- 10–15% culture-positive cases remain undiagnosed
- 40% patients diagnosed as having TB by X-ray alone may not have active TB disease

Tuberculin test may be useful as an additional tool for diagnosing pediatric TB.

PROCESS OF DIAGNOSIS

Patients with chest symptoms and other symptoms suggestive of TB, consult medical staff at governmental, non-governmental or private general health facilities.

The Medical Officer (MO) at the health facility screens the patients. All outpatients with a cough of 3 or more weeks are to be considered as tuberculosis suspects. Using the RNTCP laboratory form for sputum examination, the MO sends the suspects for sputum examination. In Medical Colleges and other hospitals, indoor-patients suspected of TB should also be referred by the treating physician using the same RNTCP laboratory forms for sputum examination.

In the laboratory the patient receives sputum containers with instructions to provide sputum samples, which are then subjected for sputum examination. If the health facility is not a DMC then the patient may be referred to the nearest DMC or else the patient's sputum is collected and transported to the nearest DMC.

Three sputum samples are collected over two consecutive days:

- Spot sample on the first day,
- One early morning sample on second day and
- One spot sample on the second day.

Sputum examination and anti-TB treatment are FREE of charge at Government Facilities under RNTCP.

The MO / health worker / laboratory technician (LT) should instruct the patient for proper sputum collection. If sputum is not collected in a correct manner and the patient has smear-positive pulmonary tuberculosis, the diagnosis may be missed, and the patient may continue to spread the infection to others.

The LT should properly label the sputum container by writing the patient's Laboratory Serial Number on the side of the sputum container and not on the lid.

- 3 sputum specimens (spot—morning—spot) should be collected over 2 consecutive days
- Sputum should be at least 2 ml in quantity and preferably mucopurulent
- Sputum samples should be transported and examined as soon as possible, and not later than seven days after collection
- Results of sputum tests should be reported within a day

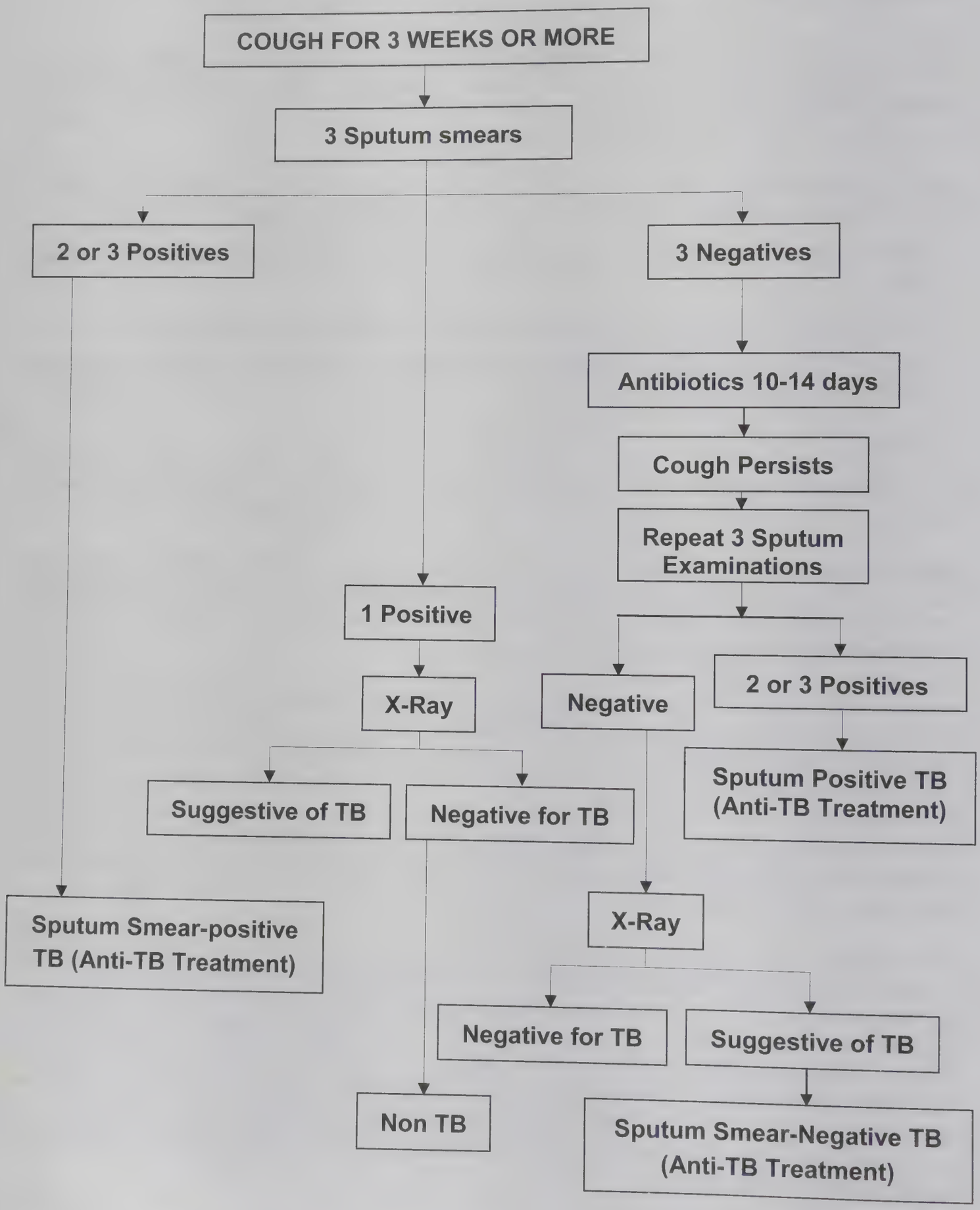
If the diagnostic algorithm given on next page is not followed, patients not having tuberculosis may be treated unnecessarily on the basis of abnormal X-rays.

Patients with three, or at least two out of three, sputum positive smear results are diagnosed by the physician as having pulmonary sputum smear-positive TB. They are further classified as a new or retreatment case based on their previous treatment history, and appropriate therapy is prescribed.

Patients with only one positive result out of three sputum smear examinations will be subjected for chest X-ray examination. Patients, who have one smear-positive and a chest X-ray compatible with TB, as diagnosed by an MO, are considered to be having pulmonary sputum smear-positive TB. If a patient has only one positive result out of three sputum samples and X-ray is normal, this may be a laboratory error, or may be due to mix-up of sputum specimens with another patient's sputum result. In a well-functioning laboratory, patients with only one out of three sputum samples positive are exceptionally rare.

If good diagnostic practices are followed as indicated above it is expected that among the new pulmonary TB cases, at least 50% will be sputum smear-positive cases. Patients in whom all 3 samples are smear-negative should be prescribed symptomatic treatment and broad-spectrum antibiotics for 10 - 14 days. In such cases antibiotics such as fluoroquinolones (ciprofloxacin, ofloxacin, etc.), rifampicin or streptomycin, which are active against tuberculosis, are not to be used. Most patients are likely to improve with antibiotics if they are not suffering from TB. If the symptoms persist after a course of broad spectrum antibiotics, repeat sputum smear examination (3 samples) must be done for such patients.

DIAGNOSTIC ALGORITHM FOR PULMONARY TB



TB cases remain undiagnosed IF

- **TB suspects are not identified among outpatients**
- **TB suspects are not sent for sputum examination**
- **Sputum microscopy is of poor quality**

If two or more smears are positive, the patient is diagnosed as having smear-positive pulmonary TB. If only one sputum sample is positive, chest X-ray is taken. If findings of the X-ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum positive pulmonary TB.

If the results for all the three sputum samples of repeat examination are found negative then a chest X-Ray is taken. If findings of the X-ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum negative pulmonary TB.

Patient suspected of having extra-pulmonary TB, and patients who are contacts of sputum smear-positive patients, should have their sputum examined for AFB if they have cough of any duration. Procedures undertaken to arrive at the diagnosis of extra-pulmonary TB must be mentioned in the Treatment Card.

Extra-pulmonary TB patients and contacts of smear-positive TB patients should have 3 sputum smears examined regardless of the duration of cough.

Patients suspected of having pulmonary TB may be referred by private practitioners to the nearest DMC for diagnosis. In such cases, the MO at the DMC will have 3 sputum smears examined to arrive at a diagnosis and then, if diagnosed to be suffering from TB, would refer the patient to an appropriate peripheral health institution for treatment. Feedback on the patient's diagnosis and treatment should be provided to the referring physician.

IMPORTANCE OF PROPERLY IDENTIFYING TB SUSPECTS

Encourage health workers and community volunteers to identify and refer pulmonary TB suspects to DMCs for early diagnosis and treatment of TB patient among them, to prevent further spread of the infection. Explain that patients with pulmonary smear-positive tuberculosis discharge tubercle bacilli into the air while sneezing or coughing. Contacts of undiagnosed pulmonary smear-positive patients can become infected when they breathe in these tubercle bacilli.

Most patients with TB visit health facilities promptly after symptoms occur. It is important that the diagnosis of tuberculosis be considered and sputum examined for them. If TB is

not suspected, patients with smear-positive pulmonary TB will not be identified. These patients will continue to spread the infection to others and if not diagnosed and treated, more than half of them will die. Hence, every adult patient with respiratory symptoms attending the health facility must be asked about symptoms suggestive of tuberculosis.

The most common symptom of pulmonary TB is a persistent cough for 3 weeks or more, usually with expectoration. It may be accompanied by one or more of the following symptoms:

- Weight loss
- Chest pain
- Tiredness
- Shortness of breath
- Fever, particularly with rise of temperature in the evening
- Blood in sputum in some case
- Loss of appetite
- Night sweats

Every patient who has cough for 3 weeks or more, with or without other symptoms, should have 3 sputum samples examined for AFB.

A person with extra-pulmonary TB may have symptoms related to the organs affected. For example:

- Swelling of lymph nodes, occasionally with discharge of pus
- Pain and swelling of the joints, if involved
- Headache, fever, stiffness of the neck and mental confusion when the brain or meninges are involved

In addition, the following general symptoms may be present:

- Weight loss
- Fever, particularly with rise of temperature in the evening
- Night sweats

At any general health facility

- **2–3% of new adult outpatients are estimated to be TB suspect.**
- **On an average, 10% of TB suspects are expected to have sputum smear-positive pulmonary TB**

Patients with extra-pulmonary TB, who have cough of any duration should have 3 sputum samples examined. If extra-pulmonary TB is suspected but not confirmed, examination of sputum, if positive can help to confirm the diagnosis. The contacts of smear-positive TB patients, having cough of any duration with or without other symptoms, should be subjected to sputum examination.

Usually, 2-3% of new adult outpatients in any general health facility will have a cough for 3 weeks or more. If a health facility is subjecting less than 2% of their new adult outpatients for sputum examination, a good number of TB patients may be left undetected. On an average, 10% of TB suspects are expected to have sputum smear-positive pulmonary TB.

EXERCISE 1

1. What is the most common symptom of pulmonary tuberculosis?

2. List the other symptoms a tuberculosis suspect may have.

EXERCISE 2

Case 1: Meena Patel

Meena Patel is 25 years old. She has come to the health care centre today because she does not feel well. By asking her questions, the health worker finds out that Meena has had cough with expectoration for 4 weeks and has felt very tired. What should the health worker suspect Meena to be suffering from?

Explain your answer.

Case 2: Shyam Meghwal

A patient has pulmonary tuberculosis and was initially smear-positive. Shyam Meghwal is the patient's brother and is 29 years old. He has come to the health care centre today with his brother. When the health worker gives the patient his drugs, he notices that Shyam is coughing. The health worker asks Shyam how long he has been coughing. Shyam says he has been coughing for one week. After further questioning, the health worker determines that Shyam does not seem to have any other symptoms of tuberculosis. Should the health worker suspect Shyam of having pulmonary tuberculosis? Explain your answer.

EXERCISE 3

At a PHI, the total new outpatient attendance is 250 per day; of which 200 are adults. On an average 12 TB suspects are referred for sputum examination per month. Comment.

COLLECTING SPUTUM FROM TUBERCULOSIS SUSPECTS

For all TB suspects attending a PHI, which is also a DMC, sputum will be collected and examined at the same facility.

If the patient is attending a PHI, which is not a DMC, there are two options:

(i) The TB suspect can be referred to his nearest DMC: or

(ii) The sputum specimen can be transported to the DMC

Whatever arrangement is most convenient to the patient and ensures prompt and quality diagnosis should be used. The number of visits that the patient has to make to PHIs and the waiting time during each such visit should be minimized as much as possible. Patients or their sputum samples should never be turned away, as far as possible. If sputum microscopy is not possible on the day that the patient visits the PHI due to any unavoidable reason, his/her sputum sample should be collected on the same day and sputum microscopy may be done on the following day.

When pulmonary TB is suspected, 3 sputum specimens (1^{st} SPOT — EARLY MORNING — 2^{nd} SPOT) should be collected and examined by smear microscopy. All the 3 specimens should be collected within 2 consecutive days, and specimens should be sent and examined at the DMC for sputum microscopy as soon as possible, and not later than 7 days.

Generally, a PHI functions as a DMC only when it covers a population of 1 lakh and has a new adult OPD attendance of at least 100 per day. In difficult areas, more laboratories are required. Hence, in such areas, a PHI may be allowed to function as a DMC even if it covers a population of 50,000 and has a new adult OPD attendance of 60-100 per day.

Guidelines for collecting sputum

- The patient is given the sputum container with Laboratory Serial Number written on its side. The person collecting the sputum demonstrates how to open and close the container, takes the patient to an open space away from other people, and demonstrates how to bring out sputum. The patient is instructed to inhale deeply 2–3 times with mouth open, cough out deeply from the chest, open the container and spit out the sputum into it, and close the container. This is the **first spot specimen**.

- The patient is given a labeled container with instructions to cough out sputum into the container early in the morning after rinsing the mouth, before breakfast. This is the **early morning specimen**.

- When the patient returns with the early morning specimen, a **second spot specimen** is collected in the same way as first spot specimen.
- To obtain good quality sputum specimens and to prevent contamination, the staff must perform certain tasks:
  - Before sputum collection,
  - During sputum collection, and
  - After sputum collection.

The following are the details of the task to be performed.

1. Tasks performed before sputum collection

Before collecting the sputum specimen, the health worker should briefly explain to the patient the reasons for sputum collection. The *Laboratory Form for sputum Examination* should be filled up completely, generally by the MO. This form is sent to the DMC along with the sputum specimens. (Only one form needs to be filled out for all 3 sputum specimens collected from a patient.) The form accompanies the patient's sputum specimens when they are transported from the peripheral health facility to the DMC for examination.

The results section, located on the bottom half (sometimes on the reverse side) of the lab form, is completed by the DMC after the sputum examinations. All the 3 sputum examination results for a patient can be recorded on this form. The top half of this form is generally completed by the MO who requests a sputum examination. The detailed description of completing the form is as follows.

Name of Referring Health Facility

The name of the referring facility (any health sector) from where the patient is being referred for sputum examination is written in the space provided.

Date

The date (day/month/year) when the patient is examined and the form is filled up, is written in the space provided.

Name of patient

The patient's full name (also nickname, if any) is written in the space provided.

Age

The age of the patient is written in the space provided.

Sex

The letter M is ticked if the patient is a male. The letter F is ticked if the patient is a female.

Complete address

The patient's full address with landmarks is written in the space provided. It is very important to write the complete address of the patients so that they can be easily traced when they do not return to the laboratory or the outpatient department of the hospital for their results.

Patient's TB No.

The Tuberculosis Number of a patient who is having follow-up sputum examined during the prescribed treatment regimen is recorded in the space provided. However, Tuberculosis Number (TB No) is not written for a tuberculosis suspect who has been referred to the DMC for sputum microscopy, since this patient has not been diagnosed with tuberculosis yet and has not been registered.

Only ONE Laboratory Form for Sputum Examination is filled out for all 3 sputum specimens collected from an individual patient

Type of suspect / Disease

Pulmonary box is ticked √ if patient is having cough and the specimen is sputum.

Extra-pulmonary (EP) box is ticked √ if sputum specimen is collected from a suspected EP TB with cough of any duration.

Reason for examination

The diagnosis box is ticked √ if the sputum specimen is collected from a tuberculosis suspect. A patient who had all three samples negative for diagnosis, was given 10-14 days of antibiotics but did not improve will undergo sputum examination again. This will be ticked √ in "Repeat diagnosis" box. The follow-up of anti-TB treatment box is ticked √ when a patient's sputum is collected as part of follow-up during his prescribed treatment period.

Name and signature of the referring person/official

The name and signature of the referring person/official who referred the TB suspect or follow-up patient is written in the space provided.

Specimen Identification Number

If specimens are being transported to a DMC from another health facility, a Specimen Identification Number is given at the referring facility, because the Laboratory Serial Number can only be assigned at the DMC. Sputum specimens are assigned specific numbers to keep track of each patient's sputum results. After the Laboratory Form for Sputum Examination is filled up, this number is written on the side of the patient's sputum container. (If a sputum specimen is separated from its Laboratory Form for Sputum Examination, a LT can find out whose specimen it is by using the Specimen Identification No. on the sputum container. The laboratory technician can then locate the form by using the date and the identification number.) Each separate specimen will generally have its own unique Specimen Identification No. For example, 3 specimens from a single patient might have Specimen Identification Nos. A1, A2 and A3. The 3 sputum specimens of the next patient may have Specimen Identification Nos. B1, B2 and B3.

Dates of sputum collection

All the dates (day/month/year) on which sputum specimens were collected is written in the space provided.

Name and signature of the specimen collector

The name and signature of the specimen collector is written in the space provided.

If sputum is collected and transported to the DMC, the list of patients whose sputum is being sent should accompany the samples and laboratory forms for sputum examination. An example of such a list is given below.

List of Patients whose sputum are sent to DMC

Health Facility: *PHI 101* Sent on*: 8/9/ 04* **Health Worker who collected specimen:** *Raju*				***DMC:*** *PHI 237*	***For DMC use*** ***Received on: 8/9/04*** ***Examined on:_____*** ***Result sent back on:***
Specimen Identification No.	**Name**	**Age**	**Sex**	**Address**	**Date of collection of sputum**
C1, C2, C3	Lakshmi Kumari	46	F	223 Gandhi Dham	6/9/04,7/9/04
D1, D2, D3	Lakshmi Pati Rao	50	M	223 Gandhi Dham	6/9/04,7/9/04
E1, E2, E3	Girija Devi	32	F	225 Gandhi Dham	6/9/04,7/9/04
F1, F2, F3	Kailash Nath	35	M	225 Gandhi Dham	6/9/04,7/9/04

2. Tasks performed during sputum collection

Person collecting the sputum specimen should follow the guidelines specified below:

- A specimen collected under supervision is likely to yield better results. The person guiding the patient for specimen collection should stand behind and encourage him to cough and produce a good quality specimen.
- Whenever possible, sputum should be collected in an open place well ventilated room meant for this purpose
- Patients are usually more comfortable if they are separated from other persons at the time of sputum collection
- The patient should be given a sputum container with the Laboratory Serial Number written on its side. If the sputum is being collected at a location other than the DMC, then the Specimen Identification Number (or patient's name) is written on the side of the container.
- For the diagnosis of tuberculosis, the three specimens of single patient "SPOT-MORNING-SPOT" are designated as "a-b-c" adjacent to lab serial number, respectively. For follow-up sputum examination of patients, two specimens of sputum are collected as "MORNING-SPOT" and these are designated as "b-a" adjacent to the lab serial number. Morning specimen is generally labeled as 'b'.
- The person collecting the specimen demonstrates how to open and close the container. The patient is instructed to inhale deeply (2–3 times), cough out sputum from the chest, spit into the container and close it.
- The person collecting the specimen should make sure that no one stands in front of the patient who is trying to cough up sputum. Sputum should not be collected in closed rooms, toilets and ill-ventilated rooms.
- When a patient has only coughed up saliva or has not coughed up at least 2 ml of sputum, the patient should be encouraged to give good specimen
- When the outside of a container is contaminated with sputum, the person collecting the specimen should wipe the container clean and destroy whatever is used to clean the container.

Tips for good sputum specimen collection

- Take the patient away from others and collect sputum in the open space or a well-ventilated room meant for this purpose

- Stand behind the patient and encourage coughing up of at least 2 ml of sputum

3. Tasks performed *after* sputum collection

The person collecting the sputum specimens should follow the guidelines specified below:

- If the sputum specimens are to be sent immediately to the laboratory, the person should put the container into a special box meant for transport
- If the sputum specimens are not being sent immediately to the laboratory, these should be stored in a cool and shady place in the referring health facility
- The person should wash hands thoroughly with soap and water every time when the material is handled.
- Patients should be told to come back to receive the results of sputum examination. Alternatively, sputum results may be sent to the referring health facility by hand.

Laboratory serial number (and/or specimen identification number) should be clearly written on the side of the sputum container.

TRANSPORT OF SPUTUM SPECIMENS

It should be ensured that after sputum is collected it is taken to the DMC and examined as early as possible (within 7 days). Arrangements should be made locally for transport of specimens to the DMC, and for sending the results to the referring health centres. The specimens should be packed carefully in a transport box to avoid spillage. Before sending the sputum specimens to the DMC, the person should verify that:

1. The accompanying dispatch list contains the necessary data for all patients and clearly identifies the referring health facility where the sputum was collected.
2. The total number of sputum specimens corresponds to the total number on the accompanying dispatch list.
3. The Specimen Identification Numbers on the sputum containers correspond to those on the accompanying dispatch list.
4. One Laboratory Form for Sputum Examination is enclosed for each patient.

The health worker should then mark the date of dispatch on the dispatch list, put the list in an envelope and attach it to the outside of the transport box.

Sputum specimens should be examined by microscopy no later than 1 week after they are collected. After sputum smears are prepared from specimens for examination, the containers MUST be disinfected and destroyed as per guidelines.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Form for Sputum Examination

Name of Referring Health Facility: _____ Date: _____

Name of patient: _____ Age: ____ Sex: M F

Complete address: _____

_____

Type of suspect / disease: ❑ Pulmonary

❑ Extra-pulmonary Site: _____

Reason for examination:

❑ Diagnosis

❑ Repeat Examination for Diagnosis

❑ Follow-up of anti-TB treatment Patient's TB No _____

(Name and signature of referring person/ official)

If sputum samples are being transported:

Specimen identification No.: _____ Date of sputum collection: _____

Specimen Collector's name and signature _____

RESULTS (To be completed in the laboratory of DMC)

Name of DMC: _____

Lab. Serial No.: _____

Date of examination	Specimen	Visual appearance (M, B, S)*	Results (Neg or Pos)	Positive (grading)			
				3+	2+	1+	Scanty**
	a						
	b						
	c						

* M = Mucopurulent, B = Blood stained, S = Saliva

** Write actual count of AFB seen in 100 oil immersion fields

Date: _____ Examined by (signature): _____

The completed form (with results) should be sent to the referring PHI within one day of the examination.

MANAGEMENT OF PATIENTS AFTER RECEIVING THE SPUTUM RESULTS

When the referring health facility receives the sputum results from the DMC, MO reviews the patients, and based on the results of sputum smear examination, classifies the patient accordingly (as shown in the "diagnostic algorithm" earlier).

REMEMBER, the health system is responsible to ensure that all diagnosed sputum smear-positive patients are traced and put on treatment within 7 days of diagnosis.

EXERCISE 4

Answer the following.

1. How many lab forms are filled up for a TB suspect?
   a. One
   b. Two
   c. Three
   d. None
2. With in how many days after sputum collection should sputum specimens be examined by microscopy?
   a. With in 1 day
   b. Not later than 3 days
   c. Not later than 7 days
   d. With in 1 month
3. Sputum examinations for two patients were conducted on 10.04.2004. The laboratory technician reports the results on 18.04.2004. Comment.

4. For an extra-pulmonary TB patient, sputum should be examined if s/he has cough for _____

a. 1 week

b. 2 weeks

c. 3 weeks

d. any duration

EXERCISE 5

In this exercise you will read about a health worker collecting sputum from a tuberculosis suspect. Assume you are observing this health worker. When you finish reading, answer the exercise questions in the space provided.

Narayani is a health worker at a PHC. It is now Monday morning. She suspects her patient Meena of having pulmonary tuberculosis. Narayani tells Meena about sputum examinations. She then fills out a Laboratory Form for Sputum Examination. Next, Narayani writes down the Specimen Identification No. A1 on the side of the sputum container.

Narayani demonstrates to Meena how to cough up sputum. Narayani stands to the side of Meena and tells her to try to cough up sputum. Meena is embarrassed to make so much noise with other patients around. Narayani takes her into a private room without any windows and successfully collects a spot sputum specimen. She closes the sputum container firmly with a lid and places it in a corner of the laboratory.

Meena returns on Tuesday for a second interview. Narayani prepares to collect a second sputum specimen. She then writes the Specimen Identification No. A2 on the side of the second sputum container. Next, Narayani reminds Meena how to cough up sputum. While Meena tries to cough up sputum, Narayani stands at the side of Meena.

After she collects the second sputum specimen, Narayani places the lid on the container and closes it firmly. She washes her hands carefully with soap.

On Wednesday, she carefully packs these sputum containers for transport. The containers are received by the microscopy laboratory on Friday.

On the basis of the information provided answer the questions on the following page.

1. Did Narayani collect the correct number of sputum specimens from Meena?
   Explain your answer.

2. Did Narayani collect sputum from Meena in a good area?
   Explain your answer.

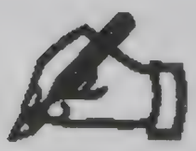
3. Did Narayani stand in the correct place when she collected the sputum?
   Explain your answer.

4. Did the specimens arrive at the laboratory within the specified time?
   Explain your answer.

5. Did Narayani need to wash her hands after she collected the sputum specimen?
   Explain your answer.

Let your facilitator know when you have completed the Exercise. He will review the answers with you.

Have a group discussion about Module 2 before beginning Exercise Workbook E1.



EXERCISE WORKBOOK E1: LABORATORY FORM FOR SPUTUM EXAMINATION

Top Section

Please open Exercise Workbook E1 at this time.

The upper portion of the form is to be completed by the Medical Officer.

For this exercise, assume that all patients are attending the same facility as the Designated Microscopy Centre, called PHI 237, except where noted otherwise. Complete only those Laboratory Forms for patients in whom sputum examination is indicated. The date is 3 September 2003. Sputum examination is not indicated for all patients. For patients in whom sputum examination is necessary, sputum will be collected on 3 September and 4 September. For ease of reference, each patient is given a letter as well as a name. This letter should be used for the Specimen Identification No. wherever required.

1. Raman Lamba (Patient A) of 7 Institutional Area, Lodhi Road, is a 24-year-old male labourer with pain in the chest for two weeks. There is no cough. Pain is worse with movements.
2. Parvathi Sinha (Patient B) of 196, Gali Paranthe Wali, Chandni Chowk, is a 16-year-old female student with non-tender swelling of the lymph nodes in the anterior and posterior areas of the left side of the neck. She reports that she has occasional cough for the past 5 days.
3. Lakshmi Kumari (Patient C) of 223 Gandhi Dham, Bapu Nagar, is a 46-year old woman who has had cough for two months with fever, sweats at night, and occasional coughing up of blood. The patient is being attended to at a remote health facility (PHI 101). Sputum will be transported to the Designated Microscopy Centre (PHI 237).
4. Lakshmi Pati Rao (Patient D) of 223 Gandhi Dham, Bapu Nagar, is the 49 year old husband of Patient C. He has had a cough for 5 years. When asked, he reports that he has received treatment for "pneumonia" several times in the past. He remembers receiving shots for a few months once, and at another time taking a medicine which made his urine turn orange. He recalls that these medicines helped him feel much better. He is seen at the same facility as Patient C (PHI 101).
5. Girija Devi (Patient E) of 225 Gandhi Dham, Bapu Nagar, is the 32 year old neighbor of Patients C and D. She encouraged both to come to health facility PHI 101 because of their symptoms. She reports a rash on her arm and says she

sneezes often. She requests sputum examination. She has no other symptoms and no cough.

6. Kailash Nath (Patient F) of 225 Gandhi Dham, Bapu Nagar, is the 35 year old husband of E. He came to health facility PHI 101 only to meet C, D and his wife E. He wants to go back home before it gets late. He is coughing and spitting blood. When asked, he reports that he has been coughing for several years.

7. Sita Devi (Patient G) of 2586 Gali No. 3, Gobind Puri, Near Gurudwara, is an 80 year old woman who complains that she feels tired. She does not have cough or fever. She has heard that people who are weak receive treatment at this centre and get better.

8. Ashok Kumar (Patient H) of No. 55 Raja Garden, near Post Office, is a 31 year old vendor who complains of cough and high fever for the past 10 days. He has otherwise been healthy, but now feels very ill, and is short of breath when he walks. He remembers that the fever came on suddenly.

9. Ghanshyam Singh (Patient I) of 124 JJ Colony, Rajiv Puram, is a 16 year old boy who has slight difficulty in walking over the last two years. His right knee is swollen. He saw a physician in town who took a biopsy which showed caseating granuloma. He could not afford treatment from the physician, and was referred to the centre for care. He has no cough.

10. Bhola Ram (Patient J) of Gobi Wali Gali No. 1704, near Mandir, is a 32 year old farmer. He has had a cough for the past 4 months. He has lost weight.

11. Man Bahadur Lal (Patient K) of Tilonia, No. 25A, is a 52-year-old man being treated for pulmonary tuberculosis at this centre (TB No. 96). Today is his last day of medication—he has completed the full six months of treatment. His sputum was positive when he began treatment and became negative after two months of treatment and after two months of the continuation phase. He brings in a sputum sample collected early in the morning.

12. Lallan Prasad Parmar (Patient L) of Gali Akara, Near Rivoli, No. 217, is a 51 year old man who was treated at this centre one year ago and was declared cured prior to the implementation of RNTCP. He now has cough and fever for the past month.

13. Visweswara Reddy (Patient M) of A 28 Kingsway Camp, is a 16 year old male who reports feeling feverish and tired for the past month. He also has a running nose and sneezing. Temperature is normal.

14. Ravindra Mehrotra (Patient N) of No. 70 Masjid Ke Pas, Sultan Bazar, is a 40-year-old woman who complains of rash on her scalp and trouble sleeping at night.

15. Kiran Kumar (Patient O) of No.15 Gulmohar Park, is a 37 year old man. He has had a cough for two months. Though he is able to carry on work, occasionally he feels feverish and has lost weight. He had come to PHI 237 on 20th August and underwent sputum examination and his three smear were found negative for AFB. His cough has not subsided in spite of 2 weeks of antibiotics.

POINTS TO BE REMEMBERED

- Undiagnosed and untreated pulmonary sputum smear-positive TB cases are the source of infection in the community, i.e. they have the potential to transmit infection to others.
- The most common symptom of pulmonary TB is a persistent cough for 3 weeks or more.
- In RNTCP, sputum smear microscopy is the main tool for the diagnosis of TB cases.
- Three sputum smears should be examined (Spot—Early morning—Spot) for diagnosis.
- Sputum should be examined within 7 days of collection and the results should be reported on the same day.
- X-ray is a supportive tool for diagnosis.
- It is important to elicit any past history of anti-TB treatment from the patient.
- Extra-pulmonary cases and contacts of all smear-positive cases with cough should be subjected to sputum examination irrespective of the duration of cough.
- 2–3% of new adult outpatients in a general clinic will be TB suspects and should be sent for sputum examination.
- On average, 10% of TB suspects are expected to have sputum smear-positive pulmonary tuberculosis.

Module 3:
Supporting Laboratory Services

MODULE 3: SUPPORTING LABORATORY SERVICES

INTRODUCTION

The District Tuberculosis Officer (DTO), the Medical Officers – TB Control (MO-TCs), and Medical Officers (MOs) of Designated Microscopy Centres (DMCs) and Sputum Collection Centres are responsible for supporting laboratory services by visiting the laboratories and performing identified activities. The Senior Tuberculosis Laboratory Supervisors (STLSs) are responsible for monitoring the activities of all the DMCs in their respective Tuberculosis Units.

Every DMC must have a Tuberculosis Laboratory Register, which should be filled up completely and accurately. From the Tuberculosis Laboratory Register one can know whether the tuberculosis suspects have had the correct number of sputum examinations done or not. The DTO, MO-TC, and STLS are responsible for verifying the quality of sputum microscopy as per protocol on Quality Assurance (QA).

The MO / STLS should monitor the maintenance of documentation related to sputum microscopy examinations. This includes explaining to Laboratory Technicians (LTs) the importance of limiting administrative errors (for example, by marking the sputum containers and slides with proper Laboratory Serial Numbers) and recording results of sputum examinations accurately.

Ensure that the DMCs and health facilities which collect and transport sputum are visited by the STLS for supervision at least once every month.

STLS is responsible for monitoring and supervision of all Designated Microscopy Centres (DMCs) in his/her TU.

MONITOR DOCUMENTATION RELATED TO MICROSCOPY EXAMINATIONS

Patients are placed on treatment regimens based on the results of their sputum smear examinations. If the results of sputum smear examinations are recorded on the Laboratory Form for Sputum Examination of some other person, the patient may be prescribed the wrong treatment regimen, treated unnecessarily, or not treated despite having TB. To limit these errors it is very important to monitor how the LTs examine and record results of sputum smear examinations, i.e. to make sure they mark the sputum containers and slides correctly with Laboratory Serial Number, and accurately record the results of sputum smear examinations on the form. Also make sure that LTs keep all

the slides *serially* in the box until the STLS reviews them for quality assurance (All slides are stored in the slide box in the same serial order as they appear in the laboratory register. If any sputum specimens are missed, the corresponding slots in the slide box may be left vacant. For follow-up specimen, the Morning sample is marked as "b" and spot sample is marked as "a" and are placed in the slide box in serial order as "a" first followed by "b"). LT should not segregate positive and negative slides. During the on-site visit, the STLS should select five smear-positive and five smear-negative slides in a systematic random manner from the TB Laboratory register and review them as per QA protocol.

Explain the importance of limiting administrative errors

If the patient's sputum specimens are not labeled properly at the health facility or if the Laboratory Form for Sputum Examination gets separated from the specimens, the laboratory technician may not know whose sputum specimens are in the containers when they reach the laboratory.

The LTs should ensure that the Laboratory Serial Number on the Laboratory Form for Sputum Examination matches with what is written on the side of the sputum container and on the slide on which smear is prepared. Other health facilities which collect specimens and transport them to the DMC should assign Specimen Identification Numbers and write it on the side of the containers.

Explain the importance of accurate recording of results of sputum smear examinations

LTs should understand the importance of accurate recording of results of sputum smear examinations on the Laboratory Form for Sputum Examination. Explain to them that patients are diagnosed and placed on the appropriate treatment regimen based on the results of their sputum smear examinations. Also, at the end of the initial intensive phase, patients have their sputum examined to determine whether they have remained smear-positive or converted to smear-negative. During the continuation phase also, smear-positive patients are monitored by microscopy examination. If sputum examination results are incorrectly recorded, it will affect the treatment given.

The following table describes how to enter the results and grading in the grading column of the form according to the number of acid fast bacilli (AFB) seen while examining the slide:

If the slide has:	Result	Grading	No. of fields to be examined
More than 10 AFB per oil immersion field	Pos	3+	20
1-10 AFB per oil immersion field	Pos	2+	50
10-99 AFB per 100 oil immersion fields	Pos	1+	100
1-9 AFB per 100 oil immersion fields	Pos	Scanty-B*	100
No AFB in 100 oil immersion fields	Neg		100

**Record actual number of bacilli seen in 100 fields – e.g. "Scanty 4"*

LTs must write all smear-positive (including scanty) results only in red ink in the Tuberculosis Laboratory Register.

Grading improves the laboratory technician's attention and facilitates supervision. It also helps to assess the load of disease. Patients who have 3+ or 2+ sputum smear examination results are less likely to convert to smear-negative by the end of the initial intensive phase, although these patients have equally high cure rates.

LTs should have little or no difficulty in reading slides that contain many AFB. However, when there are less than 10 AFB per 100 oil immersion fields, the laboratory technician may have difficulty in reading the slide. Results should be reported to the treating physician within one day after receipt of specimens.

ZIEHL–NEELSEN STAINING PROCEDURE

1. Select a new unscratched slide and label the slide with the Laboratory Serial Number with a diamond marking pencil.

2. Make a smear from yellow purulent portion of the sputum using a broom stick. A good smear is spread evenly, 2 cms x 3 cms in size and is neither too thick nor too thin. The optimum thickness of the smear can be assessed by placing the smear on a printed matter. The print should be readable through the smear. Smear preparation should be done near a flame. This is required, as six inches around the flame is considered as a sterile zone which coagulates the aerosol raised during smear preparation.

3. Allow the slide to air dry for 15–30 minutes.

4. Fix the slide by passing it over a flame 3–5 times for 3–4 seconds each time.

5. Pour 1% filtered carbol fuchsin to cover the entire slide.

6. Gently heat the slide with carbol fuchsin on it, until vapours rise. Do not boil.

7. Leave carbol fuchsin on the slide for 5 minutes.

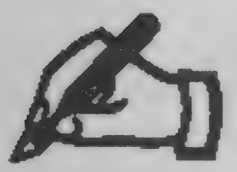
8. Gently rinse the slide with tap water until all free carbol fuchsin stain is washed away. At this point, the smear on the slide looks red in colour.

9. Pour 25% sulphuric acid onto the slide.

10. Let the slide stand for 2–4 minutes.

11. Rinse gently with tap water. Tilt the slide to drain off the water.

12. A properly decolourised slide will appear light pink in color .If the slide is still red, reapply sulphuric acid for 1–3 minutes and rinse gently with tap water. Wipe the back of the slide clean with a swab dipped in sulphuric acid,
13. Pour 0.1% methylene blue onto the slide.
14. Leave methylene blue on the slide for 30 seconds.
15. Rinse gently with tap water.
16. Allow the slide to dry.
17. Examine the slide under the microscope using x40 lens to select the suitable area and then examine under x100 lens using a drop of immersion oil.
18. Record the results in the Laboratory Form and the Laboratory Register.
19. Invert the slides on tissue paper till the immersion oil is completely absorbed. Do not use xylene for cleaning the slides, as it may give false results of repeat examination after storage.
20. Store all positive and negative slides serially in the same slide-box until instructed by the supervisor.
21. Disinfect all contaminated material before discarding.



EXERCISE WORKBOOK E1:
LABORATORY FORM FOR SPUTUM EXAMINATION

Complete the Laboratory Form: Bottom Section

Start with Laboratory Serial Number 501. The appearance of the specimen is given in brackets. Specimens are examined on 4 September 2003. Sign your own name.

Patient	No. of AFB seen (visual appearance)
B. Parvathi Sinha	30 AFB are seen in 100 oil immersion fields (mucopurulent) 6 AFB are seen in 100 oil, immersion fields (mucopurulent) 70 AFB are seen in 100 oil immersion fields (mucopurulent)
C. Lakshmi Kumari	150 AFB are seen in 50 oil immersion fields (bloody) 80 AFB are seen in 50 oil immersion fields (mucopurulent) 25 AFB are seen in100 oil immersion fields (mucopurulent)
D. Lakshmi Pati Rao	240 AFB are seen in 20 oil immersion fields (mucopurulent) 50 AFB are seen in 100 oil immersion fields (mucopurulent) 100 AFB are seen in 50 oil immersion fields (mucopurulent)
F. Kailash Nath	300 AFB are seen in 20 oil immersion fields (bloody) 200 AFB are seen in 50 oil immersion fields (bloody) 10 AFB are seen in 100 oil immersion fields (bloody)
J. Bhola Ram	400 AFB are seen in 50 oil immersion fields (bloody) 60 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent)
K. Man Bahadur Lal	0 per 100 oil immersion fields x 2 both, saliva
L. Lallan Prasad Parmar	80 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent)
O. Kiran Kumar	0 per 100 oil immersion fields x 3 (saliva, mucopurulent, saliva)

TUBERCULOSIS LABORATORY REGISTER

The Tuberculosis Laboratory Register (page 49) is used to record the results of sputum smear examinations. The LT assigns a Laboratory Serial Number for each patient who has been referred to the Laboratory for sputum microscopy. The following information about the patient is then recorded:

- Date of sputum smear examination
- Full name
- Sex
- Age
- Name of the health facility (e.g. primary health centre, medical college, private practitioner, NGO, etc.) that requested the examination
- Complete address
- Reason for examination (diagnosis, repeat diagnosis and follow-up of chemotherapy).
- Results of sputum smear examinations (results of specimens a, b and c can be recorded).

If the patient is a TB suspect being evaluated, the technician ticks the Diagnosis column under Reason for Examination. **For patients who undergo sputum examination for repeat diagnosis, the lab technician should write RE in the column for diagnosis.** If the patient is already on chemotherapy, the LT writes the patient's Tuberculosis Number (from the Laboratory Form for Sputum Examination) in the Follow-up column under Reason for Examination.

The last two columns of the Tuberculosis Laboratory Register are for the Laboratory Technician's (LT) signature and any remarks the LT or supervisor wishes to make. The remarks column is also used by the LT who, with the assistance of STS/STLS, enters TB No. and category of treatment from the TB Register for sputum smear-positive patients of same TU/district. The remarks column can also mention in brief the action taken for patients belonging to other TU/districts, e.g., "Referred to Udaipur district". In this case, as soon as the TB No. is received from Udaipur district, the TB No. along with category of treatment is entered in the remarks column, e.g., 234/04 Cat-I.

Using the Tuberculosis Laboratory Register

The MO should ensure that all smear-positive patients diagnosed are started on treatment or are referred for treatment. If any smear-positive patients have not been entered in the Tuberculosis Register and are on treatment, register them. For patients who have not been put on treatment make sure they are traced, put on treatment immediately and registered. If the patient lives outside the district, a copy of the 'Referral for Treatment' Form (Page 181) must be sent to the district where the patient will begin treatment. A 'Referral for Treatment" Register (Page 182) should be maintained in "big" designated microscopy centres (e.g. medical colleges, TB hospitals, etc.) that are referring large number of patients to other health facilities for treatment (after diagnosis). Information regarding referral of a patient should be noted in the 'Referral for Treatment" Register as well as the Remarks column of the Tuberculosis Laboratory Register.

Every week the MO in Charge (or his designate) of the DMC should review the Tuberculosis Laboratory Register to ensure that correct numbers of sputum smear examinations (i.e. 3 per TB suspect) are being performed for diagnosis. Compare sputum results mentioned in the Tuberculosis Laboratory Register with those mentioned in the TB Treatment Cards and TB Registers. You will learn more about TB treatment card and TB register in the next Module.

Up to three-sputum specimen examination results can be recorded for each patient on one line of the Tuberculosis Laboratory Register.

Check the accuracy of the Tuberculosis Laboratory Register

Laboratory staff should not use the Tuberculosis Laboratory Register to record the results of any other laboratory examinations. All results of sputum smear examinations done in a Designated Microscopy Centre should be written only in one Tuberculosis Laboratory Register, and not in any other register. Duplicate registers should not be maintained.

- **Make sure the Tuberculosis Laboratory Register is completely and correctly filled.**
- **Make sure the all smear-positive patients are started on treatment.**

Make sure that LTs are using the correct Laboratory Serial Number. A new number should be assigned to every TB suspect whose sputum is to be examined. The Laboratory Serial Number should begin with number "1" each year. The Laboratory Serial Number is written in the Tuberculosis Register as well as the TB Treatment Card. It can be used as a cross-reference when the MO of the DMC wants to cross-check the results of the sputum examination in the Tuberculosis Register with that of Tuberculosis

Laboratory Register and the TB Treatment Card. By using the name of the patient and his Laboratory Serial Number from the Tuberculosis Register, the MO of the DMC can easily find the results of sputum smear examinations in the Tuberculosis Laboratory Register. Without this Laboratory Serial Number, the MO of the DMC would have to look through many pages of the Tuberculosis Laboratory Register for a patient's sputum smear examination results.

The MO of DMC should look through the Tuberculosis Laboratory Register and make sure all the columns have been completed. For example, it may be found that a patient's address or name of referring health facility is missing or incomplete in the Tuberculosis Laboratory Register.

The MO should emphasize to the laboratory technicians about the importance of writing complete addresses of patients examined for diagnosis so that they can be traced and put on treatment.

If the sputum smear examination was intended for Diagnosis or for Repeat Examination for diagnosis of TB, the name of the health facility that referred the patient should be written in the Name of Referring Health Facility column (e.g. Dr CU Shah, Private Practitioner, or XYZ Hospital). If the TB suspect has attended the OPD of the DMC on his own, the name of the DMC should be mentioned in this column. If the sputum smear examination was for follow-up of chemotherapy, the name of the health facility where the patient is undergoing the treatment should be written in the Name of Referring Health Facility column.

The Tuberculosis Number of all TB patients, with their respective category of treatment, should be recorded in the Remarks column, and the Tuberculosis Number of all patients whose sputum is examined for follow-up must be written in the space provided.

A Laboratory Serial Number is assigned to a PATIENT, not to a SPUTUM SPECIMEN

Monthly summary

The laboratory technician should summarize the information on sputum smear examinations done during that month. This information should be summarized in the following format at the end of each month, printed in the Laboratory Register itself. The STLS should write their monthly supervisory abstract after the last entry of the month. Patients from the following month should be started from the next new page.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Register

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Complete address (for new patients)	Name of Referring Health Facility	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	a	b	c		

If sputum is examined for diagnosis, put a tick (✓) mark in the space under "Diagnosis"
If sputum is examined for repeat diagnosis, put RE in the space under "Diagnosis"
If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up"

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Tuberculosis Laboratory Monthly Abstract
(Record Numbers)

Month Year 200.	TB Suspects Examined For Diagnosis	TB Suspects Found Positive	TB suspects Undergoing Repeat Sputum Examination	TB suspects Found Positive on Repeat Examination	Follow-up Patients examined	Patients Positive on Follow up	Total Slides Examined	Total Positive slides	Total Negative slides	Signature of LT and STLS
Jan										
Feb										
Mar										
Apr										
May										
Jun										
Jul										
Aug										
Sep										
Oct										
Nov										
Dec										
Total										

Signature of the M.O.

Ensure that the patients for diagnosis had three sputum samples examined and follow-up cases had two sputum samples examined

To define a patient as smear-negative, 3 sputum specimens must have been examined. The results of all three-sputum smear examinations must be negative. If only one or two sputum specimens were examined, find out why the remaining sputum smear examinations were not done. A smear-positive patient may be missed if the third sputum is not collected and examined. To minimize the proportion of 'false' smear-negative patients, at least 3 smear-negative sputum specimens should be available.

To define a patient as smear-positive, there must be at least 2 positive sputum specimens. If only one or two sputum specimens were examined and only 1 was smear-positive, then MOs are responsible for ensuring that the patient is traced. When the patient is traced the remaining sputum specimen/s should be collected and examined. If 3 sputum specimens were examined and only 1 was smear-positive, the patient should be referred by the MO for an X-ray examination.

- **For diagnosis, 3 sputum samples should be examined**
- **For follow up, 2 sputum samples should be examined**

It must be made sure that results of follow-up sputum smear examinations, which have been recorded in the Tuberculosis Register, are accurate by comparing them with those in the TB Lab Register. Such comparisons should be made especially for patients who were smear-positive at the beginning of treatment.

Reasons for False-negative Smear Results

- Improper storage of sputum specimens
- Inadequate sputum collection
- Too thin or thick smears
- Over-heating the slide while fixing
- Insufficient fixing
- Boiling carbol fuchsin
- Over decolorization with sulphuric acid
- Improper storage of stained slides

- Inadequate examination
- Using saliva for smears
- Reading and reporting errors

Consequences

- Patients with TB may be missed and thereby patient continues to spread the disease
- Wrong categorization
- Intensive phase treatment may not be extended for the correct duration, resulting in inadequate treatment
- Patients and the community may lose confidence in the programme
- Unwarranted repetition of investigations

Reasons for False-positive Smear Results

- Faulty sputum collection (presence of food particles or fibres)
- Using old scratched slides
- Using unfiltered carbol fuschin
- Insufficient decolorization with sulphuric acid
- Contamination due to transfer of bacilli from one smear to another
- Not wiping the oil immersion lens after examination of a positive slide
- Reading and reporting errors

Consequences

- Patients without TB may be unnecessarily put on treatment
- Treatment may continue beyond the recommended duration
- Medicines are wasted
- Patients and the community may lose confidence in the programme

Follow-up sputum smear examinations

The most important method of monitoring the smear-positive cases are the follow-up sputum smear examinations which are carried out at the end of the intensive phase, extended intensive phase (if applicable) and at the end of treatment. These results determine the conversion rate from smear-positive to smear-negative at the end of intensive phase of treatment, and the cure rate.

The follow-up sputum smear examination at the end of treatment is very important for evaluation of the outcome of treatment (to determine the cure rate). Sputum should generally be collected at the time of collection of the 16^{th} blister in Cat I and III, and 20^{th} blister in Cat II of treatment so that the result is available at the time of supply of the last week's blister pack.

Follow up of sputum smear examinations of patients put on non-DOTS regimens should be done at the end of 2, 6 and 12 months.

To ensure that sputum smear examinations are actually carried out in accordance with the policy, during visits to the designated microscopy centres, compare the results of follow-up sputum smear examinations of approximately 15 patients from the TB Register with those in the Tuberculosis Laboratory Register. Results of follow-up sputum smear examinations should be entered in the TB Register within one month.

Further follow-up is not required for a patient who has completed treatment and has been declared cured .The patient should be advised to report only if symptoms suggestive of TB recur.

Schedule of follow-up sputum smear examinations for patients put on DOTS:

Category of treatment	Pre-treatment sputum	Test at month	IF: result is	THEN →
Category I	Positive	2	-	Start continuation phase, test sputum again at 4 and 6 months‡
			+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months‡
	Negative	2	-	Start continuation phase, test sputum again at 6 months‡
			+	Continue intensive phase for one more month, test sputum again at 3,5 and 7 months‡
Category II	Positive	3	-	Start continuation phase, test sputum again at 5 and 8 months
			+	Continue intensive phase for one more month, test sputum again at 4,6 and 9 months
Category III	Negative	2	-	Start continuation phase, test sputum again at 6 months
			+	Re-register the patient and begin Category II treatment

‡ : *Any patient treated with Category I , who has positive smear at 5, 6 or 7 months of treatment should be considered a Failure and started on Category II treatment afresh.*

Schedule of follow-up sputum smear examinations for patients put on non-DOTS (ND1 and ND2 regimens):

Regimen	Sputum examinations for pulmonary TB			
	Pre-treatment sputum	Test at 2 months	Test at 6 months – IF: result is	THEN
ND_1 (2SHE/10HE)	Positive	Positive	+	Failure
			-	Continue treatment
		Negative	-	Continue treatment
			+	Failure
	Negative	Negative	-	Continue treatment
			+	Failure
		Positive	+	Failure
			-	Continue treatment
ND_2 (12HE)	Negative	Positive	+	Failure
			-	Continue treatment
		Negative	-	Continue treatment
			+	Failure

EXERCISE 1

Case 1

During your visit to a DMC in your district, you review the Tuberculosis Laboratory Register. You notice that the laboratory technicians are beginning with a new Laboratory Serial Number every month. You also notice that the Address column for new patients is never completed.

Describe the activities that are being done incorrectly. In addition, mention what you should tell the technicians about the importance of maintaining an accurate Tuberculosis Laboratory Register.

Case 2

Review the sample page of the Tuberculosis Laboratory Register on the page 57.

1. List the names of patients whose sputum were examined for repeat diagnosis and who can be defined as smear-negative pulmonary TB cases (provided that a Medical Officer makes the diagnosis of smear-negative tuberculosis based on clinical and X-ray examination and decides on treatment).

2. List the names of patients who only had 2 sputum specimens examined for diagnosis and cannot be defined as smear-negative.

3. List the names of patients who were examined for diagnosis and can be defined as smear-positive.

4. List the names of patients who were examined for diagnosis and only had 1 positive sputum specimen examined. Describe what action you should take.

5. List the patients examined for follow-up whose sputum smear examinations or recordings were incorrect and explain why.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Year 2003

LABORATORY REGISTER

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Complete address (for new patients)	Name of Referring Health Facility	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	a	b	c		
499	30/3	Sita Dixit	F		H.No 211, Pocket III Mayur Vihar	Modern TB Clinic	RE		Neg	Neg	Neg	Joshi	
500	30/3	Krishna Kanth	F	54	H.No 40 Sector II, Jamnagar	Jamnagar Health Centre	√		Neg	Neg		Joshi	
501	30/3	Aswani Rai	F	39	225, Block 4, Bapu Nagar	Chest Disease Health Centre	√		3+			Joshi	
502	30/3	Abdul Hazan	M	44	GaLI No 7, J J Ram Rani Coloni	Aligarh Dispensary		20	Neg			Joshi	
503	1/4	Bhim Singh		38	H No 422, Sector III, Rohini	Modern TB Clinic		102	Neg	Neg		Joshi	
504	1/4	Alex Chopra	M	45		Good Health Centre	√		1+	1+	2+	Joshi	
505	1/4	Renu Sharma	F	37		Jamnagar Health Centre		√	1+	2+		Joshi	
506	2/4	Kumar Bhatia	M	58	BB22 / Block 4, Nehru Place	Chest Disease Health Centre	√		Neg	Neg	Neg		
507	2/4	Deepak Dhawan	M	28		Modern TB Clinic	√		1+	2+		Joshi	
508	2/4	Preeti Chandra	F	26	H.No 62, Lane No. 820, Kailash Colony		RE		Neg	Neg	Neg	Joshi	

If Sputum is examined for diagnosis. put a tick (√) mark in the space under "Diagnosis"
If sputum is examined for repeat diagnosis. put RE in the space under "Diagnosis"
If sputum is for follow-up of patients on treatment. write the patient's TB No. in the space under "Follow-up"

EXERCISE 2

Complete the pages of the Laboratory Register using the Laboratory Forms you have completed in Exercise Workbook E1.

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Complete address (for new patients)	Name of Referring Health Facility	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	a	b	c		

If sputum is examined for diagnosis, put a tick (✓) mark in the space under "Diagnosis"

If sputum is examined for repeat diagnosis, put RE in the space under "Diagnosis"

If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up"

EXERCISE 3

1. A laboratory technician wants to know about the usefulness of sputum smear grading. Can you explain it to him?

2. An STLS supplied 100 slides to a PHI. The laboratory technician listed 120 smear-negative cases and 20 smear-positive cases in the Tuberculosis Laboratory Register. Please comment.

3. Tick the correct answer. Once a sputum specimen reaches a laboratory the laboratory technician gives a Laboratory Serial No. The number is subsequently entered
   a. In the Laboratory Form for Sputum Examination
   b. On the side of the sputum cup
   c. On the slide
   d. In the TB Laboratory Register
   e. In the Treatment Card
   f. In the TB Register
   g. All of the above

4. In Ziehl-Neelsen staining
   (i) Concentration of carbol fuchsin used is
   (a) 5% (b) 3% (c) 1% (d) 10%
   (ii) Concentration of sulphuric acid used is
   (a) 25% (b) 10% (c) 1% (d) 15%
   (iii) Concentration of methylene blue used is
   (a) 1% (b) 0.1% (c) 10% (d) 1.5%

5. Ram is a laboratory technician, who has assigned a Laboratory Serial No. to each sputum specimen. What is your comment?

QUALITY ASSURANCE (QA) FOR SMEAR MICROSCOPY

RNTCP relies on sputum smear microscopy for diagnosis, for categorization of patients for treatment and assessment of their progress. Hence, the credibility, success and sustainability of the programme depend on the strength of RNTCP laboratory network. Poor quality diagnosis results in failure to detect persons with infectious TB, who will continue to spread infection in the community, or unnecessary treatment of "non-TB cases." Errors in the reading of follow up smears may result in wrong outcome of patients.

An effective quality assurance (QA) system of RNTCP sputum smear microscopy network is crucial for reliability of data generated under RNTCP. QA is a total system consisting of internal quality control (QC), assessment of performance using external quality assessment (EQA) methods, and continuous quality improvement (QI) of laboratory services.

To provide TB smear microscopy services with an "easy access for the entire population", a network of RNTCP designated microscopy centres (DMCs) with competency in acid-fast sputum smear microscopy has been established. The network of DMCs is supported by larger State TB Training and Demonstration Centres (STDCs), also referred to as Intermediate Reference Laboratories (IRLs), and overseen by three National Reference Laboratories (NRLs), viz., National TB Institute (NTI), Bangalore, Tuberculosis Research Centre (TRC), Chennai and Lala Ram Sarup Institute of TB and Respiratory Diseases (LRS), Delhi.

External Quality Assessment (EQA)

The activities of DTO, MO-TC and STLS for EQA of RNTCP lab network are on-site evaluation of DMCs, blinded re-checking of DMC's slides at DTC, and reporting the results of activities to LT and MO of DMC and to STDC promptly.

The frequency of on-site evaluation of any DMC is decided on the basis of its performance. On-site evaluation of every DMC is conducted at least once a month by the STLS of the respective TB Unit.

When poor performance is identified through any of the above-mentioned activities, additional visits by STLS are mandatory for evaluation of all laboratory procedures.

On-site evaluation of Designated Microscopy Centres

The on-site evaluation includes a comprehensive assessment of laboratory safety, condition of the binocular microscope, adequacy of supplies as well as the technical components of sputum smear microscopy, including preparation, staining and reading of smears. On-site evaluation should always include examination of 5 stained positive

and 5 negative smears selected by systematic random sampling, both macroscopic as well as microscopic.

Checklists are developed to assist supervisors during the field visit and to allow for the collection and analysis of standard data for subsequent remedial action. Copies of the checklist, duly filled in by the STLS, should be handed over to MO of DMC as well as DTO. This will provide written documentation of the visit and findings and also proposed corrective actions to monitor improvements.

Ensure that the quality assurance network for sputum smear microscopy is in place and functioning

A comprehensive checklist for on-site evaluation by DTO/MO-TC of DMCs is provided in Module 9.

Random Blinded Rechecking of Routine Slides

This EQA method provides reliable assurance that a district has an efficient sputum microscopy laboratory network supporting RNTCP. Blinded rechecking is a process of re-reading a statistically valid sample of slides from a laboratory to assess whether that laboratory has an acceptable level of performance.

Random blinded rechecking involves selection of a small sample of slides, which is representative of all slides of a DMC (both positive and negative). The results of the slides are blinded and read by a STLS not belonging to the same TU to prevent bias. The discrepant results are resolved by reading of the slides by another STLS (umpire reader). A timely feedback is provided every month to LTs and MOs of DMCs for improvement in the quality of microscopy.

Sample of feedback

Blinded rechecking report on sputum microscopy for the DMC for the last month:

Type of error	No. of false results	Slide No.
False negative		
False positive		

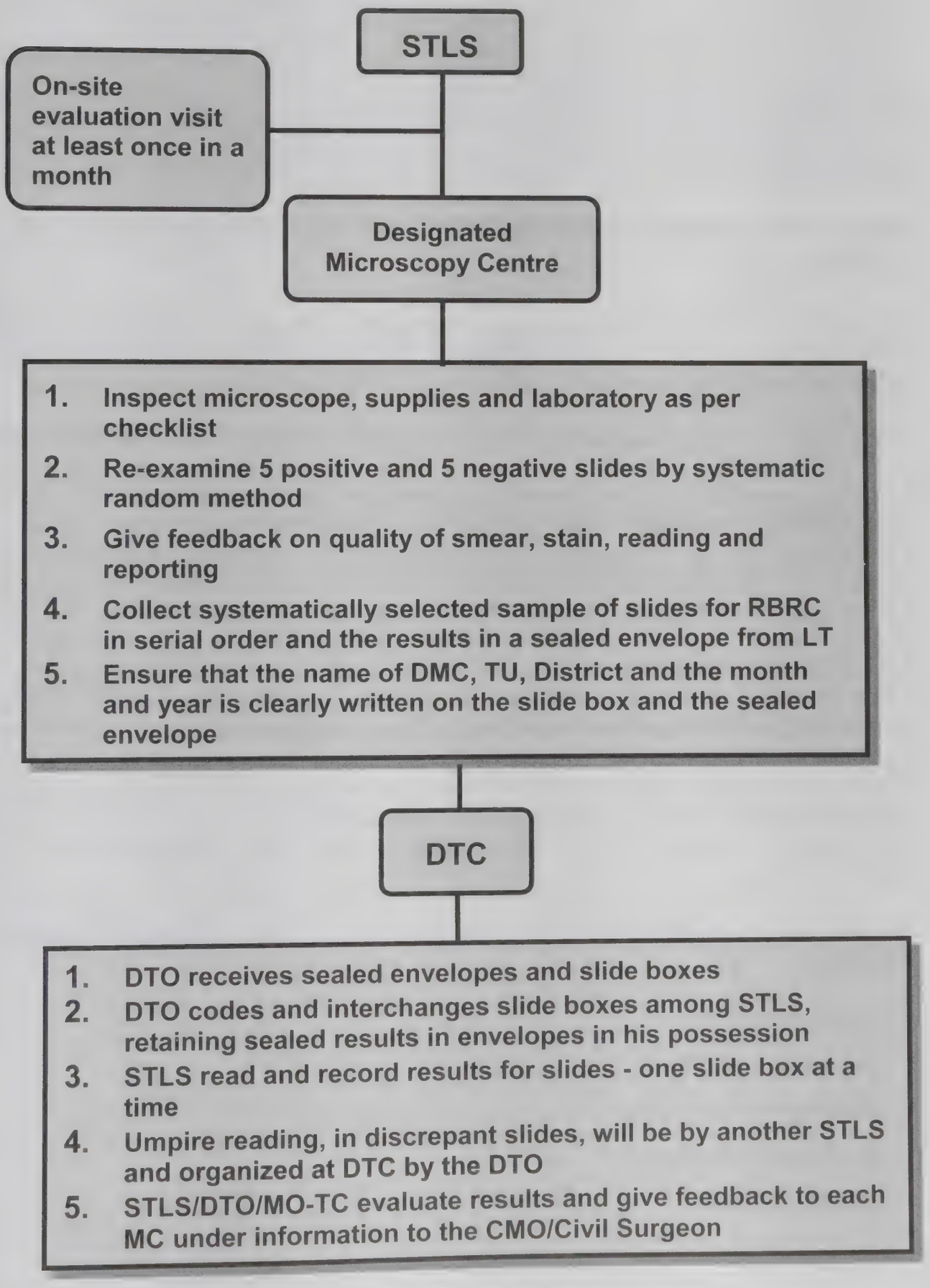
Observations and recommendations:

Signature of MO-TC/ DTO

The DTO/ MO-TC would also be supervising the DMC Laboratory as per their tour programme and summaries of their visits would be handed over to MO of DMC. Corrective actions should be implemented by the MOs as per the suggestions made by DTO/ MO-TC.

The EQA activities that need to be conducted by STLS, DTO and MO-TC are given on the next page.

Quality Assurance Network in Sputum Smear Microscopy



The Senior TB Laboratory Supervisor should:

- Visit DMCs at least once a month
- Crosscheck 5 positive and 5 negative slides
- Test the quality of smear preparation, staining, reading and recording of the LT
- Collect sample of slides for blinded rechecking at the district level

MAINTAIN AN ADEQUATE SUPPLY OF REAGENTS AND OTHER MATERIALS

The MO of DMC is responsible for determining the amount of reagents and other materials the DMC will need every month. The STLS will make sure these supplies are distributed in a timely manner, usually on a monthly basis.

Make sure there is an adequate stock of reagents and other materials in the laboratory

It is very important for the laboratory to maintain an adequate stock of reagents and other laboratory materials. If the laboratory has less stock of any items, ensure supplies are provided to the laboratory from the district or sub-district stock. Remind LTs to exhaust the old supplies before starting to use the new supplies. Old reagents should not be mixed with the new supplies. They should be kept in separate containers.

Ensure that the reagents are of good quality. It should be freshly prepared at the DTC and supplied to the DMCs. It should be re-filtered by the laboratory technicians every month. Prepared reagents should not be used beyond 4 months from the date of preparation. Purchase of commercially available 'readymade' laboratory reagents should not be made. Ensure that the binocular microscope is in good working condition and inspect and use the microscope. If it is not working properly, arrange for appropriate maintenance through DTO. If the microscope is still under warranty, get the supplier to repair it.

The following is a list of laboratory reagents, which should always be available in the laboratory:

- Carbol fuchsin (1%)
- Sulphuric acid (25%)
- Methylene blue (0.1%)
- Synthetic immersion oil
- Methylated spirit

The following is a list of other materials that should always be available in the laboratory:

- Glass slides for microscopy, and slide-boxes for storing slides
- Diamond markers (for marking the slides) and marking pens or grease pencils (for marking the sputum containers)
- Broom sticks (thick enough to make good smears)
- Transparent glass bottles for reagents (with self-adhesive labels stating date of preparation of reagents)
- Plastic tumblers/mugs
- Glass (or metal) rods (for holding slides during the staining process)
- Staining racks (for drying the slides)
- Sputum containers
- Spirit lamp or bunsen burner
- Lens paper (for wiping the oil immersion lens after examination of each slide)
- 5% phenol / 40% phenolic compound (proprietary Phenyl) diluted to 5% (for disinfection)
- Foot-operated bin (for disposal of contaminated materials)
- Timer (stop-watch)
- Laboratory Forms for Sputum Examination, Laboratory Register, "Referral for Treatment" Forms
- Filter Paper
- Fine Silk and Lint cloth
- Silica gel (hygroscopic agent) to maintain the microscope in moisture free environment (to be placed in the cabinet for Binocular Microscope)

Estimated quantity of reagents and materials required for 1000 smears

Carbol fuchsin (1%)	5000 ml
Methylene blue (0.1%)	3000 ml
Sulphuric acid (25%)	6000 ml
Immersion oil	50 ml
Phenol 5 % / 40% Phenolic compound (phenyl) diluted to 5%	200 Litres
Methylated spirit	1000 ml
Filter paper (Whatmann No. 1, pack of 100)	1 pack
Lens paper (book of 50 leaves)	20 books
Lint cloth (15 cm x 15 cm); or Fine silk (15 cm x 15 cm)*	5
Diamond marker*	4
Grease pencils or marking pens	4
Sputum containers	1100
Broom sticks	1100
New glass slides	1100
Slide Box (100 Slides)*	11
Black/ Red disposal bags of bio-degradable material	100
Silica Gel*	100 gms

* These items are reusable

EXERCISE 4

1. The following is a list of reagents and supplies for the designated microscopy centre:

Carbol fuchsin	Sputum containers
Methylene blue	Slide-boxes
Sulphuric acid	Grease pencils
Phenol (5%)	Broom sticks
Methylated spirit	

What, if anything, is missing from the laboratory's stock?

2. How should you make sure that the Designated Microscopy Centre in your TU, which examines 500 slides per month has an adequate supply of reagents and other materials? Use the quantity estimate list on page 66 for calculations.

Let your facilitator know when you have completed the exercise. S/he will review the answers with you.

ENSURE THAT CONTAMINATED MATERIALS ARE DISPOSED OF SAFELY

Sputum specimens examined in the laboratory are potentially infectious. Hence, after examination, they must be disinfected and destroyed so that the risk of infection is avoided. All disposable containers must be used only once.

Sputum cups which contain sputum can be disposed of by any one of the following methods:

1. After the sputum smears are examined, all sputum cups should be kept in a bucket containing 5% phenol solution. Caps of the sputum cups must be removed and the cups, caps and broom sticks completely submerged in the solution in a secure place for at least 12 hours. After this, the solution, cups, caps and broom sticks can be discarded with other hospital waste. This bin/bucket should have a lid which is foot operated. Similarly, used wooden sticks should also be put in the same bucket containing 5% phenol solution.

2. Incineration: Wherever incinerators exist, the type specified under Biomedical Waste Management & Handling Rules; 1998 - 2nd Amendment 2000, with combustion efficiency of 99%, it should be used. Sputum cups made of polypropylene should be used wherever available. (Note: If sputum cups are made of other varieties of plastic, they should be disinfected and destroyed as per the hospital waste management rules). Burning is not recommended.

3. Autoclaving: The sputum cups and lids, with the lids removed, along with wooden sticks can be autoclaved (or in a pressure cooker of approximately 7 litre capacity containing adequate amount of water to submerge the contents) at the end of each day's laboratory work. The autoclave cycle should have a holding time of 15 minutes at 121°C HTAT (Holding time at temperature), 10 minutes at 126°C HTAT or 3 minutes at 134°C HTAT. After proper cooling the material can be discarded with other waste in the waste disposal pit (Annexure V) of the Health centre.

4. If none of the above is available, cotton and broom sticks can be disinfected and buried at a safe distance away from inhabited areas in a landfill site ensuring deep burial as specified under Biomedical Waste Management & Handling Rules; 1998 - 2nd Amendment 2000.

5. Used slides should not be broken. They should be disposed through the hospital waste management system or in a secured pit for sharps in accordance prevailing guidelines. Slides once used for sputum microscopy should not be reused.

CONDUCT VISITS TO DESIGNATED MICROSCOPY CENTRES

Designated microscopy centres are supervised by an STLS from the sub-district. The DTO/MO-TC/MO will work with the STLS to make sure that tuberculosis-related laboratory services are properly performed. Before the visit to the designated microscopy centre, one has to plan thoroughly. During the visits, check to see that laboratory activities related to sputum smear examinations are being correctly performed and recorded by the laboratory technicians.

In this section, DTO/MO-TC/MO will learn how to prepare for visits to designated microscopy centre, review the items to check when visiting a laboratory and will develop a checklist to use during a visit to a laboratory.

Prepare for visits to designated microscopy centre

1. Decide when to visit each designated microscopy centre in the TU/district. Plan your visits in advance so that a DTO can visit all DMCs in his/her district at least every quarter and a MO-TC can visit all DMCs in his TU at least every month.

2. Decide what to check. Some important items to check are listed under point 4 (below). Review the recommendations made during previous visits and the actions taken.

3. Decide when to check each item. Some items, such as the Tuberculosis Laboratory Register, should be checked during each visit. Other items including stocks of sputum containers, slides and reagents may be checked periodically.

4. Decide how to check each item. Depending on the time available for the visit, decide the best ways to collect information:

    (i) Review the Tuberculosis Laboratory Register. Check the Tuberculosis Laboratory Register to make sure it is filled completely and accurately. Make sure that all smear-positive patients in the Tuberculosis Laboratory Register have either the TB No. mentioned in the remarks column or have the name of the PHI where the patient has been referred (if s/he belongs to another TU/district). Verify that patients who were examined for diagnosis had correct number of sputum specimens examined. Make sure that LT is writing the monthly summary correctly.

    (ii) Talk with the laboratory technicians. Make sure that they understand the importance of examining the correct number of sputum specimens. Also, make sure that they understand the importance of limiting administrative errors and accurately recording the results of sputum smear examinations on the Laboratory Form for Sputum Examination. In addition, make sure that the

laboratory technicians keep the examined sputum smear slides of all patients until the EQA procedure is completed.

(iii) Examine supplies. Check to see if there are adequate numbers of sputum containers, slides, reagents, forms and other laboratory supplies.

5. Develop a checklist. Once it is decided what to look for when one goes to the designated microscopy centre and how to check each item, it will be helpful to organize the information into a 'checklist'. In general, the checklist should be just long enough to remind the supervisor about the important items/activities that needs to be checked. It should be easy to use. Include important general information, such as the name of the centre and supervisor, and date of the visit. A more comprehensive checklist is given below. Review it now. This checklist is longer than the one that should be used during supervisory visits, but is provided for reference. You should develop your own checklist based on this.

Conduct the visit

Information should be given to the STS and STLS (particularly the latter) in advance about the visit to the designated microscopy centre. If possible, STLS and STS should be available during the visit. In the DMC, the checklist that you have prepared should be used. If you find that there is any problem, work with the STLS and STS to solve them.

CHECKLIST FOR LABORATORY SUPERVISION

Review of resources

Please write Yes/No in the column "Observation"

No	Check-points	Observations
1	Is at least one trained Medical Officer available in the health facility?	
2	Is a full-time trained Laboratory Technician (LT) available for sputum microscopy?	
3	Have provisions been made for sputum collection when LT is absent?	
4	Is a functional binocular microscope available?	
5	Has the binocular microscope undergone any servicing during last 12 months?	
6	Are all essential lab consumables available adequately, enough to last at least for one month?	
7	Is running water available for sputum microscopy?	
8	Is electricity available for the binocular microscope?	
9	Have civil works been done in the Lab as per RNTCP guidelines?	
10	Are printed reference materials on standard operating procedures available?	

Review of forms, registers, records and reports

1	Are the Lab Forms for Sputum Exams filled correctly, completely and legibly?	
2	Is the Lab Register filled correctly, completely and legibly?	
3	Is the Lab Serial Number entered correctly, starting with 1 on 1st January of the year and continuing until 31 December?	
4	Are results correctly recorded?	
5	Are there 3 sputum smears for diagnosis in at least 8 out of 10 patients?	
6	Are there 2 sputum smears for follow-up in at least 8 out of 10 patients?	
7	Are positive results written as scanty, 1+, 2+ or 3+ in red and negative in black/blue?	
8	Are results up-to-date?	
9	Does the Lab register have the summary abstract completed at the end of each month?	
10	Is there a duplicate Lab Register?	
11	Are copies of supervisory reports of Senior TB Lab Supervisor available with LT?	
12	Is there evidence of supervision by STLS on lab register?	
13	Is monthly PHI-level report on sputum microscopy and logistics being submitted by the health facility?	
14	Does the Tuberculosis Register contain all the smear-positive patients recorded in the Tuberculosis Laboratory Register? If the Tuberculosis Laboratory Register contains names of smear- positive patients which are not found in the Tuberculosis Register, do these patients belong to another TU/district?	
15	Is the Lab register consistent with the treatment cards and TB register? (Check information for at least 4-6 randomly selected new smear -positive patients.)	

Observe the Lab technician during the sputum-collection procedure

1	Did the LT check to ensure that the Lab Form was complete and correct?	
2	Is the sputum container clearly labeled on the side and not on the lid?	
3	Are each set of sputum samples from a single patient given a single Lab Serial Number?	
4	Is the Tuberculosis Number written in the space provided for all patients whose reason for examination is “follow-up” of treatment?	
5	Does the LT demonstrate to patients how to bring up sputum?	
6	Does the LT supervise patients when they provide spot sputum specimens?	
7	Does the LT visually examine the sputum provided to determine if it is sputum or saliva only?	

Observe the Lab technician preparing smears for examination

1	Does the LT use only new slides?	
2	Does the LT engrave the Lab Serial Number on each slide with a diamond marker?	
3	Does the LT use a different broom stick for each sputum smear?	
4	Are the sputum smears made on the slide of the correct size (2 cm X 3 cm) and thickness?	
5	Does the LT wait for the slide to dry before heating the slide to fix it?	
6	When the Lab technician fixes the slide by heating, does s/he do it for the proper duration of time?	
7	Is only "freshly prepared" carbol fuchsin being used, instead of ready-made commercially-available solutions?	
8	Is the carbol fuchsin free of particles and properly filtered at least every month?	
9	When the LT heats the carbol fuchsin, does s/he do it properly, avoiding boiling and allowing the slides to stand for 5 minutes after heating?	
10	Does the LT tilt the slides after rinsing with water to remove excess water?	
11	Is the sulphuric acid allowed to stand on the slide for the appropriate time period (2–4 minutes)?	
12	Is the methylene blue allowed to stand on the slide for the appropriate time period (30 seconds)?	

Observe the Lab technician examining slides under the microscope

1	While placing immersion oil on the slide, does the LT take care to avoid touching the slide with the applicator?	
2	While examining the slide with the X100 lens, does the LT take care to make sure that the lens does not touch the slide?	
3	Does the LT examine negative sputum smear slides for at least 5 minutes?	
4	Does the LT have correct knowledge about grading?	
5	Does the LT see 100 fields before declaring the smear as negative?	
6	Does the LT correctly complete the Lab Form for Sputum Examination and Lab Register?	
7	Does the LT clean the X100 lens with lens paper/fine silk after completing the examination?	
8	Are slides correctly cleaned and maintained serially in slide boxes for review by the supervisor?	
9	Are all smear-positive results recorded in red ink in the Lab Register?	
10	After examining the slides, does the LT put the sputum containers and lids (with lids removed) along with the broom sticks, into a foot-operated bucket containing 5% phenol?	
11	Does the LT break all the remaining slides of the previous month after The	

	EQA procedure is completed?	
12	Does the LT ensure that smear-positive as well as smear-negative slides are not being re-used for AFB microscopy?	

Exit-interviews of at least 2 patients undergoing sputum microscopy

1	Do the patients know how to cough out good quality sputum properly?	
2	Do the patients know when they should return for the next sputum exams?	
3	Do the patients find the timings and location of the Lab convenient?	
4	Do the patients face any difficulties for undergoing sputum microscopy?	

EXERCISE 5

Part A

In this part of the exercise you will prepare for a visit to a designated microscopy centre. You will develop a checklist to use during the visit. Include items in your checklist which actually can be checked at the designated microscopy centre you will visit.

Be sure to include the following information in the checklist:

- The date
- A space for the name and location of the laboratory
- Key recommendations of the previous visit
- The procedures you will check and whether they are correctly or incorrectly performed
- The method to be used to check each item/procedure
- A short list of the questions to ask when you are speaking to the
- Laboratory technician(s)
- A space for comments about any problems identified and possible causes
- A space for recommendations, and a space for your signature

Part B

A site visit to a designated microscopy centre may occur during this training. If so, your facilitator will give the details of the visit. Use the checklist you have developed. After the site visit, there will be a group discussion about any problems your group found and the solutions you recommend.

POINTS TO REMEMBER

- DTO and MO-TC are responsible for supporting laboratory services
- STLS is responsible for supervisory activities of all the designated microscopy centres in the sub-district
- Tuberculosis Laboratory Register should be used to record information about sputum smear results only.
- All smear-positive (including scanty) results should be recorded in red in the Tuberculosis Laboratory Register
- Do NOT re-use slides for preparing smears
- Ensure safe disposal of contaminated materials
- For one patient there is only one Laboratory Form for Sputum Examination and only one Laboratory Number even though there are 3 sputum examinations for diagnosis and 2 sputum examinations for follow-up
- Grading of smears increases the accuracy of results and reduces the possibility of errors by the laboratory technician; and facilitates supervision
- Follow-up sputum smears done at scheduled time help in monitoring treatment
- Accurate recording of results of sputum smear examinations on the Laboratory Form for Sputum Examination ensures correct diagnosis and appropriate treatment
- Ensuring quality of each and every designated microscopy centre is an essential part of RNTCP

Module 4:

Administering Treatment

MODULE 4: ADMINISTERING TREATMENT

INTRODUCTION

In the previous module we discussed the importance of sputum smear microscopy and diagnosis of TB. After establishing the diagnosis the patient should be treated effectively. The objectives of treatment are:

- To decrease mortality and long-term morbidity by ensuring cure, minimizing relapses and preventing development of drug resistance
- To decrease and break the chain of transmission of infection
- To achieve the above whilst minimizing side effects due to drugs

These objectives are achieved in RNTCP through intermittent (thrice weekly) treatment regimens given under direct observation for both pulmonary and extra-pulmonary tuberculosis patients. Treatment regimens for tuberculosis have emerged as a result of controlled clinical trials in India and other parts of the world. It has been proven that thrice-a-week (intermittent) treatment is as effective as daily treatment.

Originally it was believed that anti-tuberculosis drugs needed to be given every day to maintain drug concentrations continuously at inhibitory levels. However, animal experiments and *in vitro* studies demonstrated that certain drugs were also effective when the drug concentration dropped temporarily below that level and even after the drug had disappeared completely from the lesion or the medium. In vitro experiments demonstrated that after a culture of mycobacterium tuberculosis is exposed to certain drugs, in certain concentrations, for certain lengths of time, it takes several days (lag period) before new growth occurs. This **lag period** demonstrated by mycobacteria is the basis of intermittent treatment regimens. A series of experiments in an animal model demonstrated that intermittent dosing actually increased the efficacy of treatment. This is presumably because intermittent dosages allow organisms to re-enter the active metabolic phase in which the bactericidal drugs are more effective.

Intermittent regimens should only be used in a programme of directly observed treatment (DOT). Lack of supervision may lead to longer drug-free periods leading to development of drug resistance. Studies throughout the world and in India have shown that if treatment is not given under direct observation, at least one third of the patients do not take medicines as prescribed. The key principle for treatment of tuberculosis worldwide, and in RNTCP, is protocol-based treatment, wherein short-course standardized chemotherapy regimens are given under a programme of direct observation, called the DOTS (Directly Observed Treatment, Short-course) strategy.

Advantages of intermittent regimen

- **As effective as daily treatment**
- **Facilitates observation**
- **Less adverse reactions**
- **Reduction in total drugs consumed**
- **Less expensive**
- **Reduction in number of patient visits**

The approach of direct observation of treatment has been successful in achieving high rates of sputum conversion, high cure rates, and decrease in the infectious pool in the population, resulting in decreased transmission of infection, and prevention of drug resistance.

This module discusses how treatment is initiated and administered to patients. It includes:

- Completing tuberculosis treatment card
- Classification and typing of patients
- Treatment Categorization
- Patient flow for DOT
- Monitoring drug administration
- Management of patients interrupting treatment
- Communicating with patients
- Management of pediatric TB, Extra-pulmonary TB, TB-HIV, MDR TB patients.
- Infection control measures

TUBERCULOSIS TREATMENT CARD

Each patient who begins treatment for TB must have a Tuberculosis Treatment Card. This card contains important information about a patient, such as :

- Name, age, sex and address of the patient
- Type of disease
- Regimen prescribed
- Duration of treatment
- Amount of drugs to be given
- Results of sputum smear examinations before and during treatment
- Drugs administered during the intensive and continuation phases of treatment.
- Treatment outcome of the patient
- Retrieval actions for missing doses
- Preventive treatment for children
- Remarks

Before a patient begins chemotherapy, it is very important to find out from the patient whether s/he has **previously taken drugs** against TB. Treatment regimens differ in type and number of drugs as well as duration. A patient who has never taken anti-TB drugs (or has taken these drugs for less than one month) will start on a different treatment regimen as compared to a patient who has taken anti-TB drugs in the past for one month or more.

During the initial contact with a diagnosed TB patient, discuss disease and treatment related issues with the patient, and, if possible, with the family. The health education messages should include at least the following:

- infectious nature of TB
- treatment prescribed to cure her/him
- type of drugs s/he will be taking
- importance of directly observed treatment

- necessity of follow-up sputum smear examinations and
- screening of symptomatic contacts of smear-positive cases

Since health education is an important part of treatment administration, make sure that health workers properly communicate with the patients on a continuous basis, particularly during the intensive phase of treatment.

All efforts should be made to ensure that every dose of medicine in the intensive phase and at least the first dose every week in the continuation phase are directly observed. Treatment observation should be done by someone who is accessible and acceptable to the patient and accountable to the health system.

One of the most important responsibilities is to ensure that during the intensive phase of treatment (which is 2 to 4 months of directly observed administration of drugs) patients are swallowing every dose of their drugs under the direct observation of a DOT provider. To ensure proper drug administration, observe the DOT Provider administering drugs to the patients and speak directly to patients to determine whether they have been receiving the correct number and type of drugs. After the patients swallow their drugs in the presence of a DOT Provider, those receiving streptomycin should be given the injections with sterile syringes and needles.

Patients should be administered drugs from a DOT Centre that is close to their home. During supervisory visits to the health facilities, review the Tuberculosis Treatment Cards to determine whether these patients are regularly coming to the DOT Centres to take their drugs. Make sure that any patient who has stopped taking drugs is traced and brought back under treatment.

As part of your responsibilities in administering treatment, make sure that children under the age of 6 years in the household of a smear-positive patient are evaluated for TB and are getting proper preventive treatment if they do not suffer from the disease. If they have TB, make sure they receive the appropriate treatment.

COMPLETE TUBERCULOSIS TREATMENT CARDS

It is very important for the hospital or health facility where the patient is receiving treatment to maintain a Tuberculosis Treatment Card (see Page No 175-176) for that patient. A Tuberculosis Treatment Card can help ensure that the patients:

- Were correctly classified as having either pulmonary or extra-pulmonary TB;
- Were correctly recorded as either New, Relapse, Transfer in, Treatment After Default, Failure or Others;
- Were prescribed the correct treatment regimen and dosages;

- Had sputum smear examinations at the scheduled times;
- Were regularly administered drugs;
- Collected drugs on time; and
- Have correct outcome recorded at end of treatment

Record general patient information

It is important that the Tuberculosis Treatment Card contains all relevant and up-to-date information about the patient and her/his disease. Make sure that data are accurate. General information about a patient that is entered in the top section of the Tuberculosis Treatment Card is as follows:

State/City/District and Code district/sub-district
These are all self-explanatory. A code has been assigned by the national level to each district.

Patient TB No./ year
Write the Tuberculosis Number (TB No.) assigned to the patient when s/he was registered in the Tuberculosis Register. This number is given by the STS within one month of starting treatment. Details about Tuberculosis Register are given in the Registering Cases and Monitoring Treatment module.

Name
Write the patient's full name (with father's/husband's name).

Sex
Tick the box marked 'M' if the patient is a male and 'F' if the patient is a female.

Age

Write the age of the patient. If the patient does not know her/his age, write an estimated age.

Occupation
Specify patient's occupation, if employed. If the patient is unemployed, the same will be written in the space provided.

Complete Address
Write the patient's detailed address with description of nearby landmarks.

Name and address of contact person
Write the name and address of a person, identified by the patient, who is known to the patient and residing in same locality but not in the same household (e.g. relative, tribal

leader, village doctor, community volunteer) who can be contacted in case the patient cannot be located. Also, indicate the relationship of the contact person to the patient. However, *DOT provider cannot be considered as a contact person.*

Recording the correct address is important for:

- **Ensuring that the patient is from your area**
- **Identifying a suitable DOT center and DOT provider**
- **Retrieving a patient when she/he interrupt treatment**

Peripheral Health Institution
Write the name of the Peripheral Health Institution (PHI). A PHI is any health facility participating in RNTCP, which is manned by at least a medical officer (even if that post is currently vacant).

Name and designation of DOT provider
Write the name and designation of the person who will administer DOT to the patient. (Specify occupation / designation of community DOT provider).

DOT Centre
Specify the place where directly observed treatment will be or is being administered.

Initial home visit
Specify the details of initial home visit and address verification, which should be done before the initiation of treatment. Enter name of the person who did this in the space provided with the date of home visit.

Signature of the Medical Officer with date
The Medical Officer of the PHI where the treatment is initiated will sign in the space provided after filling up the details on the treatment card.

Studies throughout the world and in India have shown that if treatment is not given under direct observation at least one third of the patients do not take medicines as prescribed.

Record disease classification

Tuberculosis cases are classified as either *pulmonary* or *extra-pulmonary*. Pulmonary TB is characterized by the formation of lesions mainly in the lungs. Extra-pulmonary TB is tuberculosis of organs other than the lungs. Cases of pulmonary TB are subdivided into *smear-positive* and *smear-negative*. Pulmonary smear-positive TB is highly infectious. One untreated smear-positive case may infect approximately 10–15 people per year.

Patients with pulmonary smear-negative TB are also ill and should be treated. However, they are much less infectious than smear-positive patients.

If a patient has both smear-positive pulmonary TB and extra-pulmonary TB, the patient is classified as having pulmonary TB and the site of extra-pulmonary TB is written as well.

The following guidelines are used to define the patient's disease classification as pulmonary TB or extra-pulmonary TB.

Pulmonary tuberculosis

a. Smear-positive patient

A patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for acid-fast bacilli (AFB);

Or: A patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO;

Or: A patient with one sputum specimen positive for AFB and culture positive for M. tuberculosis.

b. Smear-negative patient

A patient having symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO, followed by a decision to treat the patient with a full course of anti-TB therapy;

Or: A patient whose diagnosis is based on culture positive for M. tuberculosis but sputum smear examinations negative for AFB.

Extra-pulmonary tuberculosis

Extra-pulmonary tuberculosis is tuberculosis of organs other than the lungs, such as the pleura (pleurisy), lymph nodes, intestines, genito-urinary tract, skin, joints and bones, meninges of the brain, etc.

Diagnosis should be based on one culture-positive specimen from an extra-pulmonary site, or histological or radiological, or strong clinical evidence consistent with active extra-pulmonary TB followed by the treating MO's decision to treat with a full course of anti-TB therapy.

Pleurisy is classified as extra-pulmonary TB.

The following records which may be available with the patient, will indicate whether the patient has pulmonary or extra-pulmonary TB:

- report of physical examination
- medical records
- results of X-ray examination
- results of sputum smear examinations
- report from MO

Classify the patient and tick the appropriate box on the Tuberculosis Treatment Card. If the patient has extra-pulmonary TB, write the site affected in the appropriate space on the card.

Record type of patient

Determine whether the patient who has pulmonary or extra-pulmonary TB is New, Relapse, Transfer in, Failure, Treatment After Default or Other, based on sputum examination results and previous history of treatment. Tick the appropriate box on the Tuberculosis Treatment Card. If the patient comes under the category 'Other', specify the type.

Guidelines to determine the type of patient

New
A TB patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.

Relapse
A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear-positive.

Transferred in
A TB patient who has been received for treatment in a Tuberculosis Unit, after starting treatment in another unit where s/he has been registered.

Treatment after default
A TB patient who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear-positive.

Failure
Any TB patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear-positive during treatment.

Chronic
A TB patient who remains smear-positive after completing a re-treatment regimen.

Others
TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.

If a patient is started on treatment as either a Relapse, Transfer in, Failure, Treatment After Default or Other case, a new Tuberculosis Treatment Card must be used. The patient's old Tuberculosis Treatment Card has to be kept in the health facility where the patient was originally treated till the treatment outcome is reported.

If a patient is a 'Transfer in' case, a **Tuberculosis Transfer Form** (see page 177) and a copy of the Tuberculosis Treatment Card will be sent from the "transferring unit", i.e., referring health facility / TU to the "receiving unit", i.e., health facility/ TU where the patient will receive further treatment. This form has four parts and should be filled up in triplicate. The first part of the form contains information about the patient, her/his disease, treatment details and address of the transferring unit. This information should be used to complete a new Tuberculosis Treatment Card for the patient. When the patient has reported to the receiving unit, the bottom (fourth) part of the form is completed by the receiving unit and returned to the transferring unit. The third and second parts are to communicate patients' sputum results at the end of intensive phase and treatment outcome to the transferring unit.

A **Tuberculosis Identity Card** (page 178) is completed for each patient who has a Tuberculosis Treatment Card. It is kept with the patient. Information from the Tuberculosis Treatment Card is used to complete the card. The front part of the card will have patient information, name and address of the TU/ district and treatment details of patient including classification, type, sputum results and category. The back portion of the ID card has the results of follow-up sputum examination, appointment dates for visits for drug administration and treatment outcome. This information will help to continue treatment in case the patient is transferred, or admitted to any other health facility anytime during the treatment period.

Record results of pretreatment sputum smear examinations of patients who will begin treatment for tuberculosis

The table provided for recording sputum smear results on the extreme right of tuberculosis treatment card has 4 horizontal rows for four time points. The smear results at the 4 time points are entered in the following order:

- First row is for the initial sputum result—"Pretreatment". In case of repeat sputum examination for diagnosis, the result of repeat examination should be written

- Second row is for smear result at the end of the intensive phase and extended intensive phase (if applicable) — "End IP / Extended IP".
- Third row is for smear result at the end of 2 months of continuation phase (for Categories I and II patients only)—"2 months CP".
- Fourth row is for smear result at the end of treatment—"End treatment".

There are 6 columns for entering Month, Date, DMC (Name), Lab Number, smear result and weight (of the patient) for all four time points mentioned in the rows.

When a health worker or MO suspects a patient of having symptoms of pulmonary TB, the patient's sputum must be collected and examined. The Laboratory Form for Sputum Examination is the record, which will be used to obtain information on the results of a patient's sputum smear examination. This form should be kept at the health facility where the patient will be initiated on treatment. Look at the Date column on the Laboratory Form for Sputum Examination. Write the date when the first sputum specimen was received, DMC name and Laboratory Serial Number on the patient's Tuberculosis Treatment Card under the appropriate columns corresponding to 'pretreatment' row of the table provided.

Look at the smear result column of the Lab Form for Sputum Examination. This column contains the results of the sputum smear examinations. For diagnosis there should be 3 sputum specimen examinations done for every patient. If all 3 results are negative, write NEG under the **smear results** column. If the patient's results are positive, write the highest grade of positivity in the smear result column in red ink.

Record the patient's weight

The weight of the patient is written next to the appropriate month at each follow-up.

Record history of previous anti TB treatment

Prior to treatment categorization it is essential to elicit history of previous treatment with duration and record it in the space provided.

Determine the category of treatment

Treatment is given according to categories. The information needed for categorization of a TB patient includes: disease classification; results of sputum smear examination; history of previous treatment; type of case; and severity of illness. These categories must be strictly adhered to.

Basis for the regimens in each category

Category I: This category is generally prescribed to new sputum smear-positive patients. They have a high bacillary population with higher chances of having naturally occurring drug resistant mutants. Therefore, four drugs are prescribed during the intensive phase.

Category II: These are cases who have had previous anti-tuberculosis treatment. Therefore, the chances of harboring resistant bacilli are higher. Hence, a 5 drug regimen is prescribed in the intensive phase, and the total duration of treatment is 8 months.

Category III: These are sputum smear-negative cases with a low bacillary population. There is a lower chance for drug-resistant mutants. Therefore, a 3 drug regimen is prescribed.

It is very important to elicit history of previous anti-tuberculosis treatment to help define a case; to identify patients with increased risk of acquired drug resistance; to prescribe appropriate treatment; and for epidemiological monitoring.

Severity of TB disease

The severity of the disease depends on the bacillary load, the extent of the disease, and the anatomical site of the disease. The involvement of an anatomical site helps in classifying if the disease is severe, depending on whether it is life threatening or has high risk of developing subsequent severe handicap or both.

The following forms of extra-pulmonary TB are classified as "seriously ill":

- meningitis
- pericarditis
- peritonitis
- bilateral or extensive pleural effusion
- spinal TB with neurological involvement
- intestinal
- genito-urinary
- co-infection with HIV

- All forms of pediatric extra-pulmonary TB other than lymph node TB and unilateral pleural effusion are considered to be seriously ill.

The following forms of smear-negative pulmonary TB are classified as seriously ill:

- miliary TB
- extensive parenchymal infiltration
- co-infection with HIV
- cavitary disease
- All forms of pediatric sputum smear-negative pulmonary TB except primary complex

Any patient, pulmonary or extra-pulmonary, who is known to be HIV positive based on voluntary sharing of results and / or history of anti-retroviral therapy, is considered as seriously ill. **For the purpose of categorization, HIV testing should not be done. Also, HIV status should not be revealed / recorded in any RNTCP documents.**

Patients are classified into three categories for the purpose of treatment. The number of drugs and the duration of treatment are different in the three treatment categories of RNTCP. Please review the following table carefully.

Treatment Regimens

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill** new sputum smear-negative Seriously ill** new extra-pulmonary	$2H_3R_3Z_3E_3$+ $4H_3R_3$
Category II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default Others***	$2H_3R_3Z_3E_3S_3$ + $1H_3R_3Z_3E_3$ + $5H_3R_3E_3$
Category III	New Sputum smear-negative, not seriously ill New Extra-pulmonary, not seriously ill	$2H_3R_3Z_3$ + $4H_3R_3$

* *The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows: H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh 60 kg or more receive additional rifampicin 150 mg.*

Patients who are more than 50 years old receive streptomycin 500 mg. Patients who weigh less than 30 kg, receive drugs as per body weight. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.

** *Seriously ill also includes, any patient, pulmonary or extra-pulmonary who is HIV positive and declares his sero-status to the categorizing/ treating medical officer. For the purpose of categorization, HIV testing should not be done*

*** *In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be categorized as 'Others' and given Category II treatment.*

Patients who have been previously treated are at an increased risk for having isolates of *M. tuberculosis* which are resistant to anti-TB drugs. For this reason, they are given a more intensive regimen. Experience in India and elsewhere has shown that Category II (CAT II) treatment, if taken regularly by the patient, is effective and results in cure of most patients. Patients who relapse generally have better outcomes than those who are **'Failure'** or 'Treatment After Default' cases, but even these latter types of patients generally respond well to treatment, provided they take it regularly.

Treatment is extended for an additional month if sputum smears are positive at the end of the intensive phase (2 months for CAT I patients, 3 months for CAT II patients). If a patient receiving CAT III regimen has a positive sputum smear at the end of month 2, s/he should be recorded as a Failure, re-registered and treated with the CAT II regimen afresh. CAT I and CAT II patients who have positive sputum smears at the end of the intensive phase and who, therefore, receive one additional month of intensive phase treatment, receive the same duration of treatment in the continuation phase — 4 months for CAT I patients and 5 months for CAT II patients.

Category I: All new cases who are sputum smear-positive or seriously ill patients with smear-negative or extra-pulmonary disease.

Treatment: Treatment is given in two phases. The intensive phase consists of isoniazid, rifampicin, pyrazinamide and ethambutol given under direct observation thrice a week on alternate days and lasts for 2 months (24 doses). This is **immediately** followed by the continuation phase, which consists of 4 months (18 weeks; 54 doses) of isoniazid and rifampicin given thrice a week on alternate days with at least the first dose of every week being directly observed. If the sputum smear is positive after 2 months of treatment, the 4 intensive phase drugs (H, R, Z and E) are continued for another one month (12 doses) before starting the 4- months (18 weeks) of continuation phase. If the sputum smear is positive after 5 or more months of treatment, the patient is declared as a **Failure** and is placed on CAT II treatment afresh.

Category II: All retreatment cases, viz., Relapse, Failure, Treatment After Default and Others are included in this category.

Treatment: Treatment is given in two phases. The intensive phase consists of two months (24 doses) of isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin, all given under direct observation thrice a week on alternate days, followed by one month (12 doses) of isoniazid, rifampicin, pyrazinamide and ethambutol, all given under direct observation thrice a week on alternate days. This is immediately followed by the continuation phase, which consists of 5 months (22 weeks; 66 doses) of isoniazid, rifampicin and ethambutol given thrice a week on alternate days, with at least the first dose of every week being directly observed. If the sputum smear is positive after 3 months of treatment, the 4 oral intensive phase drugs (H, R, Z and E) are continued for another one month (12 doses) before starting the 5-month continuation phase.

Category III: New patients who are smear-negative, or who have extra-pulmonary TB and are not seriously ill.

Treatment: Treatment is given in two phases. The intensive phase consists of isoniazid, rifampicin and pyrazinamide given under direct observation thrice a week on alternate days and lasts for 2 months (24 doses). This is immediately followed by the continuation phase, which consists of 4 months (18 weeks; 54 doses) of isoniazid and rifampicin given thrice a week on alternate days, with at least the first dose of every week being directly observed. If the sputum smear is positive after 2 months of starting treatment, the patient is considered a treatment failure and begun afresh on CAT II treatment.

Drugs are supplied in patient-wise boxes (PWB) containing the full course of treatment, and packaged in blister packs. The PWB have a color code indicating the category (Red for CAT I, Blue for CAT II and Green for CAT III). In each PWB, there are two pouches one for intensive phase (A) and one for continuous phase (B). For the intensive phase, each blister pack contains one day's medication. For the continuation phase, each blister pack contains one week's supply of medication. The drugs for extension of the intensive phase (prolongation pouches) are supplied separately.

Information on dosage is provided in the chart given below

Medication	Dose (thrice a week)***	Number of pills in Combipack
Isoniazid	600 mg	2
Rifampicin	450 mg*	1
Pyrazinamide	1500 mg	2
Ethambutol	1200 mg	2
Streptomycin	0.75 g**	-

* *Patients who weigh 60 kg or more at the start of treatment are given an extra 150 mg of rifampicin*

** *Patients over 50 years of age are given 0.5 g of streptomycin*

*** *Adult patients who weigh less than 30 kg receive drugs in patient-wise boxes from the weight band suggested for pediatric patients*

Treatment regimens and dosages for children with active TB are generally similar to those of adults (refer to page 134).

Regimen for non-DOTS (ND) treatment in RNTCP areas

In RNTCP areas, most/all patients would be getting DOTS regimen. However, RNTCP-non-DOTS treatment (self administered non rifampicin containing regimen) may be needed in exceptionally few cases (e.g. adverse reaction to rifampicin and pyrazinamide). To facilitate registration of patients started on RNTCP's non-DOTS regimens, a Tuberculosis Treatment Card should be filled. Up to a maximum of **5**% of patients may get non-DOTS treatment in an RNTCP area. However, this is an admission of failure of the programme to ensure convenient and effective treatment observation and should be gradually phased out. The justification for initiating patient on non-DOTS treatment should be specified in the "Remarks" column of the treatment card and TB register. The prescribed non- DOTS treatment regimen and dosages are presented below.

Treatment	Type of patient	Regimen
Non-DOTS Regimen 1 (ND1)	Smear-positive pulmonary Smear-negative pulmonary, seriously ill Extra-pulmonary, seriously ill	2HSE +10HE
Non-DOTS Regimen 2 (ND2)	Smear-negative pulmonary, not seriously ill Extra-pulmonary, not seriously ill	12 HE

Non-DOTS Regimen 1 (ND1): 12-months conventional chemotherapy regimen, with streptomycin given in the first 2 months. This is given to patients who are:

1. Sputum smear-positive pulmonary TB and

2. Seriously ill cases of smear-negative and extra-pulmonary TB (See page 87)

The treatment consists of 12-month conventional chemotherapy. The initial intensive phase lasts for 2 months and the continuation phase for 10 months. Isoniazid and ethambutol are self-administered by the patient daily for 12 months. Streptomycin is administered daily in the initial intensive phase.

Dosage for adults is one tablet of isoniazid (300 mg) and one tablet ethambutol (800 mg) every day. The dosage for streptomycin injection is 0.75 g per day (0.5 g for those over 50 year of age). Those who weigh less than 30 kgs receive dosages calculated as per body-weight.

Non-DOTS Regimen 2 (ND2): 12-months conventional chemotherapy regimen, without streptomycin for:

Patients with smear-negative pulmonary TB who are not seriously ill; and

Patients with extra-pulmonary TB who are not seriously ill

The treatment consists of 12-month conventional chemotherapy. Isoniazid (300 mg) and ethambutol (800 mg) are self-administered by the patient daily for 12 months.

Side effects of Anti-TB drugs

Serious side effects of anti-TB drugs are less with intermittent chemotherapy. Drugs should *not* be administered on empty stomach. DOT providers should be aware of the common side effects so that they can identify these early and report to the medical officer. Patient should be informed that intake of rifampicin causes reddish-orange discoloration of urine and this should not cause any alarm. Any side effects reported during treatment should be recorded in the remarks column of the treatment card.

Table 1: Symptom-based approach to evaluation of possible side effects of anti-TB drugs used in RNTCP

Symptom	Drug (abbreviation)	Action to be taken
Gastrointestinal upset	Any oral medication	Reassure patient Give drugs with less water Give drugs over a longer period of time (e.g. 20 minutes) Do not give drugs on empty stomach If the above fails, give antiemetic if appropriate
Itching	Isoniazid (H) (Other drugs also)	Reassure patient If severe, stop all drugs and refer patient to MO
Burning in the hands and feet	Isoniazid (H)	Give pyridoxine 100 mg/day until symptoms subside
Joint pains	Pyrazinamide (Z)	If severe, refer patient for Evaluation
Impaired vision	Ethambutol (E)	STOP ethambutol, refer patient for evaluation
Ringing in the ears	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Loss of hearing	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Dizziness and loss of balance	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Jaundice	Isoniazid (H) Rifampicin (R) Pyrazinamide (Z)	STOP all drugs, refer patient for evaluation

In cases of jaundice, all anti-TB drugs should be stopped immediately and the patient referred for evaluation.

Table 2: Management of TB patients on DOT in special situations

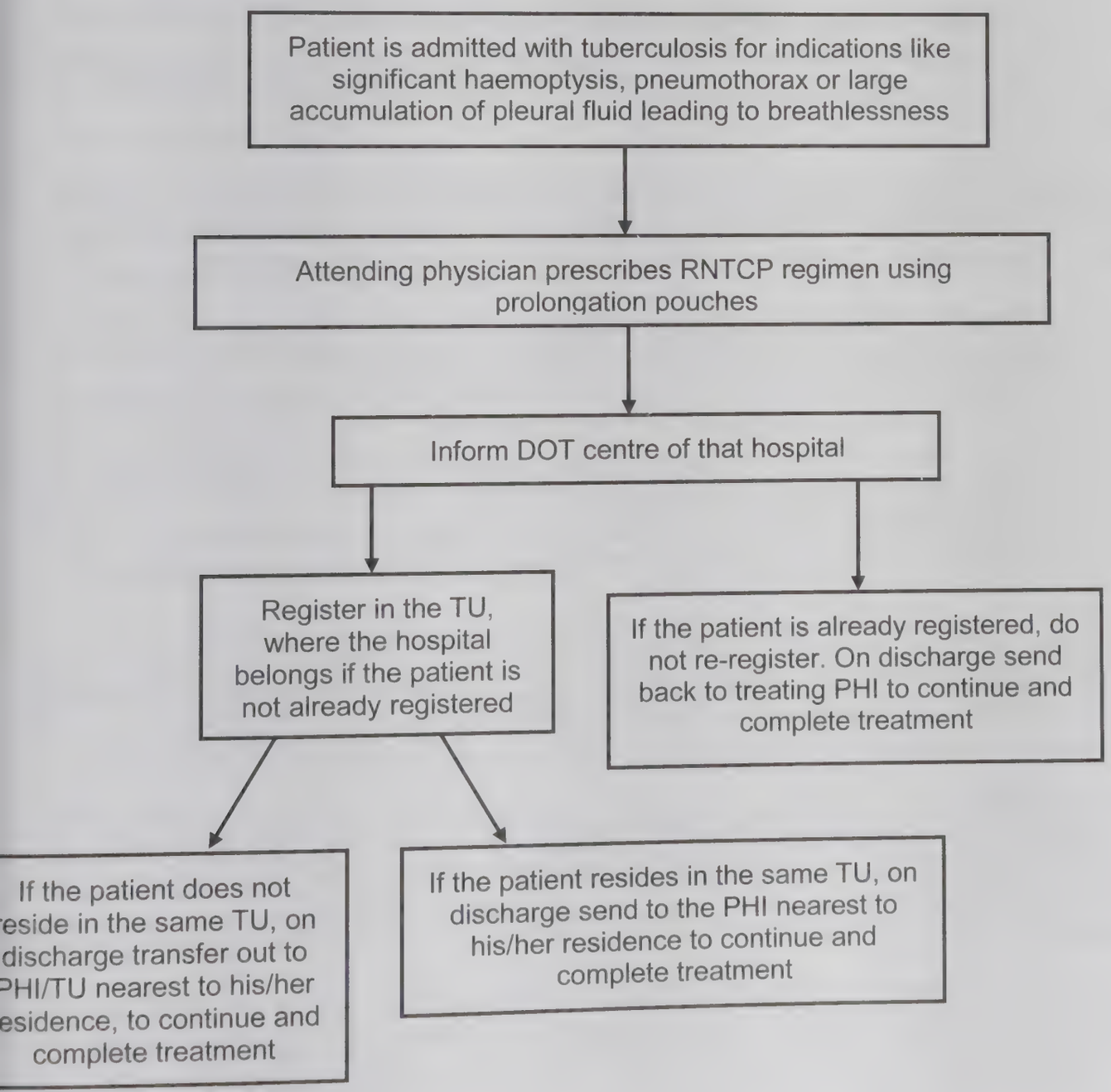
Situation	Management
Hospitalization	Only extremely ill patients need hospitalization during the treatment Patients with significant haemoptysis, pneumothorax or large accumulation of pleural fluid leading to breathlessness need to be hospitalized Flow chart for hospitalized patients is given on page 95
Tuberculous meningitis	Fatal if untreated Patient should be referred to the hospital Total duration of treatment is 8–9 months. The continuation phase should be given for 6–7 months Steroids should be given initially and gradually reduced over 6–8 weeks
Treatment of TB during pregnancy and postnatal period	Streptomycin should not be given; other drugs used in RNTCP are safe Breast feeding should continue regardless of the mother's TB status Advise the mother to cover her mouth, if she is smear-positive, while breastfeeding the baby Chemoprophylaxis for the baby is advisable if mother is sputum smear-positive (see page 134)
Treatment in patients with renal failure	Rifampicin, isoniazid and pyrazinamide can be safely given Streptomycin and ethambutol, if given, should be closely monitored with reduced dosage
Treatment in women taking oral contraceptive pills	Rifampicin decreases the efficiency of oral contraceptives; increase the dosage of the oral contraceptive or switch to another method of contraception
TB and HIV	Anti-TB Treatment is same for HIV-infected people as it is for HIV negative TB patients DOT assumes greater importance for HIV infected patients All new TB cases who are known to be HIV positive based on voluntary sharing of results and/or history of anti-retroviral therapy are considered to be seriously ill Patients with TB-HIV should complete their TB treatment prior to beginning ART (if not already on ART). If patient is already on ART, it should be modified to be rifampicin-friendly (For further details, refer to Annexure 2 Page137)
Pediatric TB	Refer to Annexure 1 Page 132
MDR TB	MDR-TB is drug resistant TB caused due to bacilli resistant to Isoniazid and Rifampicin, with or without resistance to other anti TB drugs. Management of MDR –TB is very complex Prevention of MDR–TB rather than its treatment is the priority under RNTCP Refer to Annexure 4 Page 142)

Breast feeding should continue regardless of the mother's TB status

Hospitalization of TB patients

Some TB patients may need hospitalization during their illness. All indoor patients are to be treated with RNTCP regimens. The treatment is given using prolongation pouches which will be supplied by District TB Officer through the STS of that TU. On discharge, patients may be given a maximum of three doses (1 week drug supply) to cover the intervening period prior to their continuation of treatment at their respective DOT Centre, which may/not be in the same district, hence ensuring no interruption in treatment. All indoor patients treated under RNTCP, should be registered under the local TU in which the hospital is located. (Refer to the flow chart below for Management of Indoor Patients).

Management of Hospitalized patients



There are often questions about regimens and dosages. Discuss as a group any questions or doubts you may have about anti-TB treatment as recommended in RNTCP.

Record prescribed regimens, tablets and dosages

There are two sections where the prescribed regimen and dosages of drugs for the patient in the Tuberculosis Treatment Card is to be written: one for the intensive phase of treatment on the front of the card, and one for the continuation phase of treatment on the back of the card.

Usually, the MO of the PHI (where the treatment has to be initiated) will decide which treatment regimen a patient should be prescribed. S/he will tick the appropriate box on the patient's Tuberculosis Treatment Card indicating the prescribed regimen.

It is also important to make sure that the correct number of tablets/ capsules and the amount of streptomycin are recorded on the patient's Tuberculosis Treatment Card. Patients who weigh 60 kg or more are given an extra 150 mg dose of rifampicin. Patients over 50 years of age are given 0.5 g of streptomycin. Also patients who weigh less than 30 kgs receive 0.5 g of streptomycin and dosages of other drugs are reduced as per body weight. Base the dosage of rifampicin on the patient's pretreatment weight, which should be recorded on her/his treatment card. Dose of streptomycin in Cat II patients and additional 150 mg capsule of rifampicin will be recorded in the treatment card.

If a patient's weight increases to 60 kg or more during the course of treatment, the dosage of his treatment regimen should not be modified

During visits to the health centres, make sure that the correct regimen box was ticked on the Tuberculosis Treatment Card. Compare this with the patient's Disease Classification, Type of Patient and sputum smear examination results. For example, if a patient was diagnosed as new pulmonary smear-positive, s/he should be prescribed CAT I treatment regimen.

INTENSIVE PHASE (FRONT OF CARD)

Prescribed regimen and dosages
Determine whether the patient should be prescribed CAT I, CAT II, CAT III treatment, and tick the appropriate box. Write the amount of streptomycin (in grams or milligrams) the patient will receive thrice a week during the intensive phase of treatment below the appropriate category.

CONTINUATION PHASE (BACK OF CARD)

Prescribed regimen and dosages
Write the number of tablets/capsules the patient will receive thrice a week during the continuation phase of treatment in the box next to the appropriate regimen. Tick the appropriate category (CAT I, CAT II or CAT III).

Management of the Tuberculosis patient

Patient flow for DOT

After receiving the sputum results, the MO of the Peripheral Health Institution (PHI) takes the following measures:

- establishes the diagnosis of tuberculosis
- decides the type of patient and category of treatment
- explains to the patient about:
  - the disease
  - the treatment (dosage schedule, duration, common side-effects and methods to prevent them)
  - examination of contacts (especially, if patient is smear-positive)
  - frequency of monitoring of progress until cure
  - importance of directly observed treatment (DOT)
- determines the DOT Centre and the DOT Provider (both of which should be accessible and acceptable to the patient and accountable to health system)
- initiates the Tuberculosis Treatment Card (in duplicate) and the TB Identity Card
- arranges for the transfer of patient-wise box to the DOT Centre along with the TB treatment Card, TB Identity Card and sputum containers for morning samples of follow-up sputum examinations.

For the purpose of identifying an ideal DOT provider and an appropriate DOT Centre, a DOT Directory should be maintained at PHI level. This directory should contain a locality-wise list of DOT Centres / DOT Providers in the area. It should be updated regularly. DOT can be provided by anyone other than the patient's family members. However, only such persons should be made a DOT-Provider who stay in the area of the DOT Centre. Government field workers can work as DOT-Providers or as link workers between the community DOT-Providers and the PHIs.

If the patient is to be given DOT by a Peripheral Health Worker (PHW) / community DOT Provider, a duplicate card will be prepared and given to the PHW. The MO of the PHI will give the patient-wise box (which contains drugs for the entire duration of treatment) to the PHW. Issue of this medicine box to the PHW will be duly recorded in the drug stock register maintained at the PHI. The PHW visits the house of the patient as soon as possible (in no case more than a week later) for confirmation of the address and has a detailed dialogue with the patient and other members of the family, emphasizing on points similar to the ones mentioned above (for the MO-PHI). This opportunity should also be used for screening of contacts. The initial home visit should be recorded in treatment card in the space provided. A convenient location for drug administration and a suitable DOT provider is decided mutually by the PHW and the patient.

Patients should be visited by the peripheral health worker before commencement of treatment. Treatment should be started only after the visit has been made by the PHW.

If DOT is to be given by a community DOT provider then the PHW will hand over the duplicate TB treatment card and TB identity card, along with sputum container (for morning samples of follow-up sputum examinations) and PWB to him/her. The place identified for DOT (DOT Centre) and name and designation of the DOT provider should be entered in treatment card in the space provided. On the spot training has to be done for the community DOT provider, if untrained, by the PHW, regarding directly observed treatment, adverse reactions, follow-up sputum examination and recording drug intake, before starting treatment. The DOT provider should also be trained to give health education and motivation messages to the patient. The PHW is responsible for supervising and ensuring DOT and updating of the original card at the PHI on a fortnightly basis. In case the patient misses any dose, PHW would have to take retrieval actions in case the community DOT Provider fails to retrieve the patient. The MO of the PHI (where treatment card was initiated) and the STS should also supervise DOT on a regular basis. DTO and MO-TC should support them in their efforts through field-visits.

During the intensive phase of treatment, each and every dose of medicine is to be taken under direct observation of the DOT Provider. DOT is administered at a DOT centre, which is a place convenient to both patient and DOT provider. However, rarely, a patient may be bed-ridden and hence unable to come to a DOT center. In such circumstances,

DOT should be administered under supervision at the patient's home by the PHW or community DOT Provider.

Only under exceptional circumstances can unsupervised drug administration be allowed (for a limited number of doses). For instance, if a patient is being discharged from hospital after initiation of treatment, s/he will have to be provided with 3 doses of treatment so that her/his treatment does not get interrupted during her/his transfer to a nearby PHI. In such circumstances, the entries for the unsupervised doses should be encircled on the Tuberculosis Treatment Card and the reason for the same should be stated in the **Remarks** column of the treatment card.

The DOT provider records the days the drugs are administered in the Tuberculosis Treatment Card at the time of drug intake, and refers the patient to the Designated Microscopy Centre (DMC) when follow-up sputum examinations are due. S/he also enquires about drug reactions and, if necessary, refers the patient to the MO.

Responsibility of administration of streptomycin injections at the periphery can be entrusted to the Auxiliary Nurse Midwife (ANM) or equivalent at the sub-centre level or to any registered medical practitioner who is acceptable and accessible to the patient. If this is not possible, the patient has to come to the PHC, CHC, or any other nearest health institution. The streptomycin injection should be given using disposable or sterilized syringes and needles. Water-for-injection should be made available.

During the continuation phase (CP), at least the first dose of the week must be administered under direct observation. The patient collects rest of the drugs for the week from the DOT Provider and consumes them at home.

When the patient returns the next week for her/his next blister pack, s/he must present the empty blister pack of drugs that were consumed at home. The DOT provider should collect the empty blister pack and keep it in the patient's PWB.

Sputum smear microscopy is much more informative than radiology in monitoring the progress of chemotherapy. Hence, the patient should be referred for follow-up sputum examinations at the prescribed intervals. Other investigation like ESR, antibody detection etc. are unreliable and has no role in diagnosing and/or evaluating the progress or results of treatment.

Action for patients who interrupt treatment

If a patient does not report as scheduled during treatment, visits should be made to the patient's home to bring her/him back under treatment. This should be done by the DOT-Provider no later than the day after the patient was due to come for treatment in the intensive phase, i.e. **within 24 hours, and within 7 days in the continuation phase**. It is very important to take action on patients who miss doses promptly after knowing that the patient has missed the doses. Delays in retrieval actions can lead to irretrievable

loss of the patient. This action taken to retrieve such patients has to be recorded in the space provided at the back of the treatment card with details of the retriever, date/time of attempted retrieval and the outcome of such efforts.

If the DOT Provider is unsuccessful in retrieving such patients, it should be reported to next level of supervisors (e.g. MPW, MO-PHI, STS, MO-TC etc.). If the patient misses DOT on two occasions in the intensive phase, DOT Provider should arrange a visit by the MO-PHI to the patient's home, so that the MO-PHI can review the reasons for the same, give intensive counseling to the patient and, if required, ensure that DOT is made more convenient for the patient.

If the patient does not return for treatment within 2 months, despite all efforts, the outcome of treatment should be recorded as " defaulted" in the "remarks" column of the treatment card (along with proper reasons) and the medicine box should be returned to the PHI, and thereafter to the DTC for reconstitution.

The health worker should discuss problems with the patient and find ways of preventing from missing doses, convince the patient that **cure from disease depends on regular drug intake** and convey the same message to relatives so that they can take interest in ensuring regular intake of drugs by the patient. The patient should not be blamed. Try to understand her/his difficulties and then motivate accordingly. It is best to negotiate a plan for cure with the patient. Motivation and health education of the patient should be reinforced periodically during the course of treatment.

If a patient in the intensive phase (IP) does not take medication as scheduled, s/he should be traced and given the medication on the next day. The medication for the following day is then given as scheduled. For example, if a patient is receiving DOT on Mondays, Wednesdays and Fridays, but does not take medication on Wednesday, the patient should be found on Thursday and given medication (late dose), and should take the next dose of medication on Friday, returning to the previous schedule.

If a patient entirely misses any dose of medicine (doesn't come on two consecutive days in IP or 7 days in CP), these doses must be made up at the end of the scheduled period.

The category wise dose schedule for IP and CP is given in the table below: CAT I and III treatment consists of total 78 doses and CAT II treatment consists of 102 doses.

Category	IP - Blisters and doses	Prolongation of IP*	CP	
			Blisters	Doses
Cat I	24	12	18	54
Cat II	36	12	22	66
Cat III	24	[redacted]	18	54

** Prolongation of IP for one month (12 doses) is given to CAT I and II patients who remain positive at the end of Intensive Phase*

The number of doses must be strictly adhered to. Under no condition should the 24 scheduled doses (36 in case of CAT II) extend beyond 3 months (4 months for CAT II). In case the intensive phase is extended by one month (4 weeks) because of a positive smear at the end of the initial intensive phase, this should be completed within 6 weeks. If the treatment extends beyond this period, intensive counseling should be given to the patient and patient has to be seen by the MO-PHI. A patient who is very irregular in spite of intensive efforts by the MO-PHI may have to be discontinued from rifampicin-containing regimens and may have to be started on non-DOT regimens. The outcome of such patients will have to be mentioned as "Defaulted" and the patients will have to be re-registered for non-DOT regimens in the TB Register. However, such cases would be extremely rare in a good programme.

In DOT Centres with large numbers of patients, Tuberculosis Treatment Cards should be organized according to the day of scheduled observation and the phase of treatment (i.e. one box for intensive phase and one box for continuation phase). When the patient swallows the medication under direct observation, the Tuberculosis Treatment Card should be placed after the divider for the next scheduled observation (e.g. from Monday to Wednesday during the intensive phase). In this manner, the Tuberculosis Treatment Cards of patients who do not present for treatment will be apparent on the same day, facilitating appropriate action for retrieval of patients.

When a patient returns to treatment after interruption, the health worker must review reasons for interruption carefully. Corrective actions should be taken accordingly to prevent recurrence of interruption. The treatment prescribed after interruption of treatment depends on the type of patient, the duration of treatment taken, the length of interruption, and whether s/he is smear-positive or smear-negative when s/he returns for treatment. Refer to the following tables for patients who have interrupted treatment. It is not necessary to memorize these tables. However, the tables should be readily available in all PHIs for easy reference.

For non-DOTS treatment in RNTCP areas

Determine the regimen to be prescribed ND1 or ND2 and mention on the treatment card.

Table 2: Management of patients who were *smear-negative* at diagnosis and who interrupt treatment

Treatment received before interruption	Length of interruption	Do a sputum Smear examination	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 months	No	—	—	—	Resume Treatment and Complete All doses
	2 months or more	Yes	Neg	—	—	Resume Treatment
			Pos	Default	New	Begin CAT I afresh
More than 1 month	Less than 2 months	No	—	—	—	Resume Treatment and Complete All doses
	More than 2 months	Yes	Neg	—	—	Resume Treatment and Complete All doses
			Pos	Default	Treatment After Default	Begin CAT II Treatment afresh

Table 3: Treatment for New smear-positive cases who interrupt treatment (Category I)

reatment eceived before erruption	Length of interruption	Do a sputum Smear examination	Result of sputum Smear examination	Out-come	Re-registration	Treatment
s than onth	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	No	—	—	—	Start again on CAT I**
	8 weeks or more	Yes	Positive	Default	New	Start again on CAT I**
			Negative	—	—	Continue CAT I*
months	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT I
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II*
			Negative	—	—	Continue CAT I*
e than onths	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	Yes	Positive	Default***	Other	Start on CAT II**
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II**
			Negative	—	—	Continue CAT I*

* *A patient must complete all* ***24 doses*** *of the initial intensive phase. For example, if a patient has to continue his previous treatment and he took 1 month of treatment (12 doses) before interrupting. He will have to take 1 more month (12 doses) of the intensive phase treatment. The patient will then start the continuation phase of treatment.*

** *A patient who must start again will* restart treatment from the beginning.

*** *Although this patient does not strictly fit the definition of default. Default most closely describes the outcome of this patient, although at re-registration the patient should be categorized as 'Other'.*

Table 4: Treatment for smear-positive retreatment cases who interrupt treatment (Category II)

Treatment received before interruption	Length of interruption	Do a sputum Smear examination	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	No	—	—	—	Start again on CAT II**
	8 weeks or more	Yes	Positive	Default	Treatment After	Start again on CAT II**
			Negative	—	—	Continue CAT II*
1-2 months	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT II
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II**
			Negative	—	—	Continue CAT II*
More than 2 months	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	Yes	Positive	Default***	Other	Start again on CAT II**
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II
			Negative	—	—	Continue CAT II*

* *A patient must complete all 36 doses of the initial intensive phase.*

** *A patient who must "start again" will restart treatment from the beginning.*

*** *Although this patient does not strictly fit the definition of default. Default most closely describes the outcome of this patient, although at re-registration the patient should be categorized as 'Other'.*

Record results of follow-up sputum smear examinations

Two sputum specimens are taken each time for follow-up sputum smear examinations at specified intervals: at the end of the intensive phase, two months into the continuation phase and at the end of treatment. Results must be available by the end of the intensive phase and end of treatment. For example, in CAT I, a sputum container is given to the patient at the time of the 22nd dose, the container with the early morning specimen and a spot specimen is collected at the time when the 23rd dose is given, so as to have results available when the patient comes to take the 24th dose. Similarly, collect 2 sputum samples (early morning—spot) two weeks before the end of treatment, so that the patient can be told about the sputum results and her/his treatment outcome when s/he comes to collect the medicine for the last week. The results of follow up sputum smear examination done at the end of treatment should be available not later than one week of completion of treatment, so that appropriate outcome for the patient can be given in the TB Treatment Card. **The outcome should be recorded in the TB register within one month of the last dose of treatment.**

During follow-up sputum smear examinations, if 2 specimens are examined and one of them is positive, the patient is considered smear-positive. If both specimens are positive, the higher grade out of the two results (for example 2+) is written on the patient's Tuberculosis Treatment Card. If both specimens are negative, the patient is smear-negative and NEG is recorded in the appropriate space. The schedule of sputum examinations is given in Module 3, page no 54.

A patient who is diagnosed as pulmonary smear-positive case will have her/his sputum examined at the end of IP (2 months in CAT I and 3 months in CAT II of treatment). If the patient is smear-negative (after 2 / 3 months of treatment, respectively), the date, name of DMC, laboratory serial number and sputum smear result should be recorded next to the row "End IP / Extended IP" on the tuberculosis treatment card.

If the patient is smear-positive after 2 months of treatment in CAT I (3 months in CAT II), forward slashes (/) should be drawn on the Tuberculosis Treatment Card in the row "End IP / Extended IP" under all columns. All details of sputum examination done after the end of IP should be entered *above* the "slash" in the corresponding space. The intensive phase of treatment consisting of $H_3R_3Z_3E_3$ should continue for another 4 weeks. Prolongation Pouches containing 12 blister packs of HRZE will have to be used for this purpose. At the end of the additional 4 weeks of the intensive phase of treatment (i.e. at the end of 3 months of treatment in CAT I and 4 months in CAT II), sputum smears should be examined. All details of sputum examination done after the end of extended IP should be recorded *below* the forward slash under the appropriate columns (see diagram below).

Month	Date	DMC	Lab. No.	Smear result	Weight
End IP/Extended IP	17/3 / 16/4	Pushkar / Ajmer	164 / 234	1+ / NEG	45 Kg / 46 kg

Thereafter, sputum will be examined at the end of 5 months in CAT I and 6 months in CAT II, i.e. when the patient has completed 2 months of CP. Finally, sputum will be examined at the end of treatment.

A patient who is diagnosed as a pulmonary smear-negative or extra-pulmonary (not seriously ill with cough) will have her/his sputum examined after 2 months of treatment and at the end of treatment. If a patient on category III is found to be smear-positive at the end of 2 months, the patient should be placed on re-treatment regimen (CAT II) and re-registered as failure.

Record drug administration in intensive phase

A chart on the front of the Tuberculosis Treatment Card is used to indicate the days (1-31) on which a patient takes her/his drugs during the Intensive Phase of treatment. The months in which the patient will be administered drugs during the intensive phase are written under the **Month** column in the drug administration table on the bottom of the Tuberculosis Treatment Card. The appropriate box (1–31) is ticked (✓) after the drugs are administered and streptomycin injection is given (if applicable) thrice a week to the patient under direct observation.

Record drug administration and collection in continuation phase

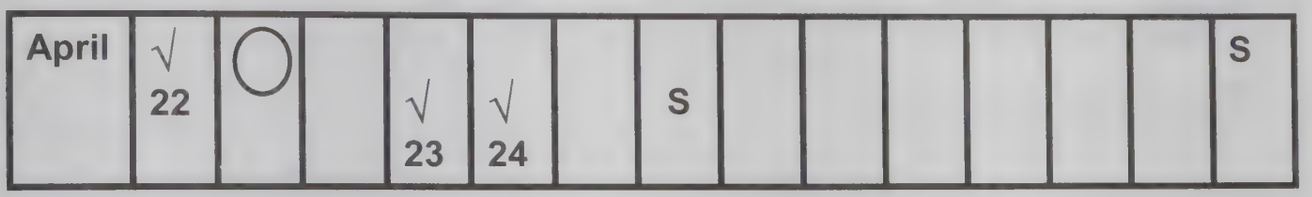
On the back of the tuberculosis treatment card, there is a chart to indicate when a patient collects her/his drug during the continuation phase of treatment. During the continuation phase of treatment, all patients collect drugs once a week on a designated day. One dose is administered under direct observation on the day of collection and the next two doses of the week are given to the patient for self- administration. The months in which the patient will be collecting drugs during the continuation phase are written under the Month column in the table at the back of the Tuberculosis Treatment Card. An **'X'** is entered in the appropriate box (1–31) to indicate the day the drugs were swallowed under direct observation. A line is drawn through the remaining days of the week (after the X) to indicate that the drugs for the remaining period of the week have been given (**X**--------).

For non-DOTS treatment in RNTCP areas (in intensive as well as continuation phases)

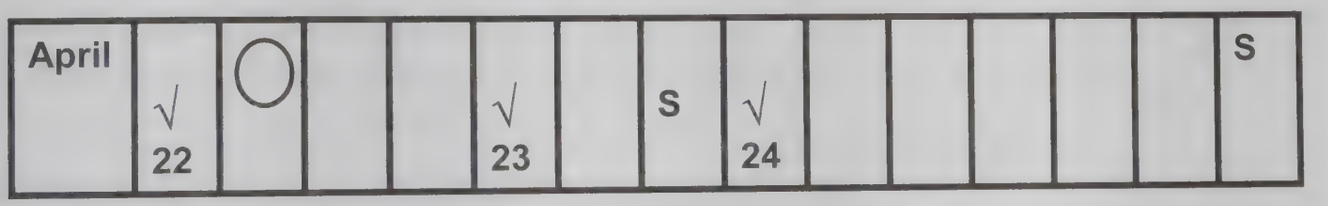
Write **C** on the date when drugs were collected by the patient and draw a horizontal line (**C**----------) to indicate the period for which drugs were supplied for self-administration.

Monitor drug collection and recording

Patients must take all doses of treatment, in both intensive and continuation phases. For example, if a patient being treated under CAT I misses the 23rd dose of the intensive phase, but is given that dose on the following day, this would be recorded as follows:



If, on the other hand, the dose is entirely missed and the patient does not report to the health facility on the next day, then the dose is given on the next scheduled day, as follows:



Refer to the tables on pages 102-104 for management of patients who interrupt treatment for longer periods of time, i.e. more than 2 weeks.

The reason/s for which any dose has been missed, and the actions taken to retrieve the patient for treatment, should be recorded in the "Retrieval action for the missed doses" table of the Tuberculosis Treatment Card.

In the same manner, if the patient misses a weekly drug collection in the continuation phase completely (i.e. for an entire week), the treatment is given and recorded as follows:

During the continuation phase, if the patient is late by a single day for drug collection, the dose may be given and other doses taken as scheduled. However If the patient is late by two days or more from the date on which s/he was scheduled to collect the drugs, the drugs are given when s/he returns for treatment and the drug administration (of the first dose) and collection (of the other two doses) are recorded as follows.

Monitoring of drug administration can be done by comparing the stock of drugs available in the patient-wise boxes with the dosages given and marked in the Tuberculosis Treatment Card. Any observed variation should be looked into and remedial measures taken.

Record treatment outcome

Identify a patient's treatment outcome by reviewing her/his Tuberculosis Treatment Card. Write the outcome and the date the patient stopped treatment in the appropriate column. The date a patient stopped treatment is the last date s/he should have taken the drugs s/he collected in the last week of collection. The last date on which a patient collects drugs is marked with an X' (or 'C' for non-DOTS) on the drug collection chart in the Tuberculosis Treatment Card. A horizontal line extends to the last date s/he should have taken her/his last dose in the blister pack. This is the date to be entered as the date of outcome.

Use the information on the Tuberculosis Treatment Card and the Table below to identify patient's treatment outcome.

Table 2: Determination of treatment outcomes

If the patient	Then identify the treatment outcome as
Was registered as pulmonary smear-positive, completed treatment and had negative smear results on 2 occasions, one of which is at end of treatment	Cured
Was registered as pulmonary smear-positive, completed treatment with negative smears at the end of the intensive phase but none end of treatment	Treatment completed
Was registered as pulmonary smear-negative or extra-pulmonary, and completed treatment	
Was known to have died from any cause whatsoever while on treatment	Died
Was registered as pulmonary smear-positive CAT I, and was smear-positive at 5 months or later*	Failure
Was registered as pulmonary smear-positive CAT II (retreatment), and was smear-positive after five months of CAT II treatment	
Was registered as pulmonary smear-negative or extra-pulmonary on CAT III, but was smear-positive any time during treatment*	
Has not taken drugs for more than 2 months consecutively any time after starting treatment	Defaulted
Was transferred to another district with Transfer Form sent and treatment outcome not available	Transferred out

**Also, re-register immediately as Category II and begin the retreatment regimen*

Every patient MUST have ONE and only ONE Treatment Outcome

Other details in the treatment card

The following details are entered in the *appropriate spaces* provided at the back of the treatment card:

- Results of X-ray examination for smear-negative pulmonary TB and investigations for extra-pulmonary TB (such as histopathology report on lymph node examination)
- Treatment outcome with date and signature.
- Details of number of children under the age of 6 years in contact with a smear-positive case who are prescribed preventive chemotherapy or treatment.

- Details of retrieval actions taken for patients missing one or more doses /collections in the intensive or continuation phase of treatment.

Record remarks

Any other relevant information about the patient can be written in the space for "Remarks". Remarks can include:

- Reasons for considering the patient as seriously ill
- Adverse drug reactions
- Reasons for unsupervised dose(s)
- Reason for discontinuation of drug collection (e.g., patient transferred to another district)

MONITOR DRUG ADMINISTRATION

For patients to be cured or treated successfully, they not only need to be prescribed the correct regimen, but they must also take all their drugs for the full duration of treatment.

During the intensive phase of treatment, health workers must directly observe intake of all doses. They should make sure that each patient swallows the drugs. Once patients swallow their drugs, those patients who receive streptomycin should be given the injections with *sterile syringes* and *needles*.

DOT Centres should have

- supply of clean drinking water with tumblers and jugs.
- adequate and convenient sitting arrangement for DOT where drug administration can be observed
- a place for safe storage of PWBs and Treatment Cards

When you visit any health facility that provides DOT, observe whether the health workers administer drugs to the patients under direct observation and whether they make sure that sterile syringes and needles are used. In addition, talk with the patients separately to determine whether they have been receiving the correct number and type of drugs. Emphasize the importance of directly observed treatment (DOT) to the health workers as well as the patients during every visit.

Ensure proper drug administration

Periodically, during supervisory visits, look at a patient's Tuberculosis Treatment Card to see the drugs s/he should be getting, and then observe the health workers administer the drugs. Health workers must give tablets to the patient according to what is written on her/his Tuberculosis Treatment Card. They must observe intake of drugs to make sure that the patient has swallowed the drugs. After distributing drugs to each patient, streptomycin injections should be given to the patients on CAT II treatment (except for pregnant women). By giving the injection after the drugs, it is ensured that the patient has swallowed all her/his drugs.

If the health worker does not administer the drugs properly, inform her/him of the correct procedure.

Since it is likely that the health worker will administer the drugs properly in your presence, another option is to meet the patient separately to determine if s/he is receiving the correct number and type of drugs. To do this, refer to the patient's Tuberculosis Treatment Card to determine the drugs s/he should be taking. Then, in private, ask the patient to describe how s/he is receiving the drugs. If you cannot determine from the patient's response whether the health worker is administering the drugs properly, ask the patient specific questions, such as:

- How many tablets, capsules and injectables are you receiving?
- How do the drugs look like?
- When are you given the drugs?
- How are you given the drugs?
- Are the drugs given under direct observation?
- Do you have to pay for the drugs?

It is very important to make sure that each patient receives the correct number and type of drugs, especially during the intensive phase of treatment when the patient's sputum should convert from smear-positive to smear-negative. There are many reasons why patients may not receive the correct number and types of drugs. Some of them are:

- health workers may not have directly observed the drug intake;
- health workers may have forgotten to give patients all their tablets or may have given them the wrong number of tablets;
- injections may not have been given to patients who were prescribed streptomycin;

- health workers may not have given the tablets to the patients before the injection;
- health workers may have given only certain drugs they like, to the patient, for whatever reason; and
- health workers may be making their patients pay for their drugs, and therefore, the patients without money do not receive all the prescribed drugs.

If you discover that some patients are not receiving their drugs properly, speak with the health worker who is responsible for administering the drugs. Stress the importance of patients receiving the correct number and types of drugs during the intensive phase of treatment so that they can convert from smear-positive to smear-negative.

It is important to visit patients at their homes in order to make general inquiries about their well-being and treatment. Patients' homes may also have to be visited to make specific inquiries about the cause of death, failure or treatment interruption.

Review Tuberculosis Treatment Cards

During your supervisory visits to the health facilities, review the frontside of the Tuberculosis Treatment Cards of all patients in the intensive phase. Verify that each patient came to the health facility to take her/his drugs on the correct days. If a patient did not come to take her/his drugs for one day, a circle should be marked on the Tuberculosis Treatment Card for that day.

If a patient on ambulatory treatment in the **intensive phase** has not taken her/his drugs for **two consecutive days of collection of DOT**, look at the backside of the Tuberculosis Treatment Card. See if there are any remarks health workers might have written (in the table of retrieval action for missed doses) to suggest why the patient has not taken her/his drugs. If there is no indication of the reasons for the patient's absence, ask the health worker whether s/he has visited the patient's home. Health workers should go to the patient's residence to trace and get her/him back under treatment. If the health worker cannot find the patient, s/he might try to locate the patient's contact person whose name and address is listed on the patient's Tuberculosis Treatment Card. The contact person might know where the patient is at present.

After administering drugs, health workers should look through the Tuberculosis Treatment Cards of all the patients who were due to come that day and put aside the Tuberculosis Treatment Cards of those patients who did not come for treatment. A health worker should trace these patients within 24 hours after treatment interruption and try to get them back under treatment. Medical Officer of the health facility should visit the homes of patients who interrupt treatment repeatedly in order to inquire about the reasons and to take corrective actions.

Similarly during supervisory visit review the back of the Tuberculosis Treatment Cards of all patients in the **continuation phase** of treatment. Verify that each patient came to the health facility to collect her/his drugs on time. If not, look for any remarks health workers might have written (in the "Retrieval action for missed doses" table). They may suggest why the patient has not collected her/his drugs. A health worker should trace this patient within 7 days if there is no indication of a reason for the patient's absence.

Exercise 1

Case 1: Raju

Review the TB Treatment Card on page 114 and give your comments

Revised National Tuberculosis Control Programme

Treatment Card

State Andhra Pradesh
Name Raju
Sex M ☑ F ☐ Age 52
Complete Address Krishna Rao

City / District with code Thiruvalur
Occupation _____

Name of the TB unit with code _____
Patient TB No / Year: 4299
PHI: _____
Name and designation of DOT provider _____
DOT centre _____

Name and Address of Contact Person Krishna Rao, Sarpanch
Initial home visit by _____ Date _____

Signature of MO with date _____

Disease Classification
- ☑ Pulmonary
- ☐ Extra Pulmonary

site _____

Type of patient
- ☐ New
- ☐ Transfer in
- ☑ Treatment after default
- ☐ Relapse
- ☐ Failure
- ☐ Other (Specify) _____

Month	Date	DMC	Lab No.	Smear Result	Weight
Pretreatment	4/4	A	128	2^+	
End IP/ Extended IP	29/5		246	1^+	
2 Months CP	26/7		210	NEG	
End treatment	30/9	S	506	NEG	

H/o previous Anti-TB treatment with duration _____

I. INTENSIVE PHASE - Prescribed regimen and dosages:

Tick (✓) the appropriate Category below

Category I ☑
New Case
(Pulmonary Smear-Positive, Seriously ill Smear-negative, or seriously ill extrapulmonary

3 times / week

H	R	Z	E

Category II ☐
Retreatment, (relapses, failure, treatment after default, Others)

3 times / week

H	R	Z	E	S

Category III ☐
New Case
(Pulmonary Smear-negative, not seriously ill: or extra-pulmonary, not seriously ill)

3 times / week

H	R	Z

Tick (✓) appropriate date when the drugs have been swallowed under direct observation

Month / Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
April 97						S	✓		✓		✓		S	✓		0	✓		✓	S	✓		✓		✓		S	✓		✓	
May 97	✓		S	✓			✓		0	✓	S		✓		✓		✓	S	✓		✓		✓		S		0		✓		
June 97								S																							

COMMUNICATE WITH PATIENTS

Good communication between a TB patient and the staff who treat the patient is very important. For a patient to be cured, s/he needs to:

- be prescribed the correct treatment regimen, and
- take all her/his prescribed drugs regularly for the total prescribed treatment period.

It is very important for the patient to know the duration of her/his treatment and understand the necessity of taking *all* her/his prescribed drugs regularly. Tell the patient that s/he will continue to spread TB if s/he does not take all her/his drugs. Inform the patient that although TB is a life-threatening disease, if the prescribed treatment is taken for the complete duration, it is curable.

Explain to the patient that TB treatment is only effective if s/he takes all her/his drugs for the entire period prescribed. It is dangerous to take only part of the prescribed drugs because in such cases the disease may become incurable.

It is therefore very important that health education is provided to the patient so as to make her/him understand the importance of taking complete treatment. Health education should be imparted when the information is being filled in the TB Treatment Card is completed for the first time and should be given periodically during the course of treatment. The necessity of direct observation of every dose of drugs taken during the intensive phase and the first dose of the weekly blister pack during the continuation phase should be emphasized to the patient. Also explain the importance of sputum smear conversion at the end of 2(3) months and at the completion of treatment.

Reassure the patient that anti-TB drugs are generally safe. Explain to the patient that urine and tears may turn orange–red as a result of one of the pills, but that this is harmless and normal and is not permanent.

Always speak respectfully to patients. Reassure them frequently that TB is curable. Emphasize that direct observation of treatment is as important as the drugs themselves. The real purpose of direct observation is to develop a human bond with the patient and not to mechanically watch the patient swallow the drugs. Remember that patients are in need of a friend; reassure them that they are being provided effective, high-quality curative care. Constantly during treatment, remind patients of how much weight they have gained, to what extent their cough has decreased, and how well they are looking now. Spend time getting to know patients' problems. Encourage patients by telling them what proportion of the treatment they have finished. Always remind patients of the next appointment. Patients who are treated respectfully develop trust not only in their treatment observer but also in the health system as a whole and are less likely to default. **In RNTCP, the patient should be the VIP not only in theory but in practice also**.

Determine if a patient has been previously treated for tuberculosis

It is very important to determine if the patient has been previously treated for TB. If the initial interview of the patient does not provide enough information on her/his medical history, s/he could be prescribed the wrong regimen. For example, a pulmonary smear-positive patient who was previously treated for TB might omit information about her/his past treatment if s/he does not understand why it is important to tell this to the interviewer. Then, instead of being prescribed the required retreatment regimen (CAT II), s/he could be incorrectly placed on a regimen for new patients (CAT I), which may lead to death or failure of treatment.

It is very important to verify with the patient that the information about the "Type" of patient has been correctly recorded so that you can make sure s/he has been prescribed the correct treatment regimen.

To do this, ask the patient if s/he has been treated for TB in the past. Ask every patient if s/he has ever taken injections for more than one or two weeks (streptomycin is likely) or taken a medicine, which turned the urine orange–red (rifampicin is likely). If you think a patient is hiding her/his past treatment for TB, explain that new patients do not receive better drugs than retreatment patients and that wrong treatment history can lead to failure of treatment and even death. When a previously diagnosed and partially treated smear-positive patient begins treatment again, s/he must take the drugs prescribed under the retreatment regimen to be cured. The retreatment patient needs a stronger regimen than a new patient to be cured.

Provide health education to patients

During initial contact

During your first contact with a patient, you will give the patient essential information about her/his disease. Make sure s/he feels comfortable enough to ask you what s/he does not understand. Keep in mind that the patient is probably very sick and might still be feeling disturbed about having the disease. Ask the patient essential questions throughout the discussion to make sure s/he understands what is being said. During later discussions with the patient, you will explain more details.

The topics to be discussed initially with the patient are as follows:

What is tuberculosis?

Explain in simple terms what TB is and what type of TB the patient has (for example, TB of the lungs). Reassure the patient that if the prescribed treatment is taken for the complete period, TB *is* a curable disease.

Counselling during the initial contact is very important to ensure proper compliance to treatment.

- **Treatment of tuberculosis**

  Explain about the TB treatment, such as:

  - Duration of treatment
  - Frequency of the patient's visits to the health facility for treatment
  - The place where the patient will receive treatment
  - Treatment is free of charge and of high quality at DOT Centres

- **Necessity of directly observed treatment (DOT)**

  Explain the importance of taking DOT. This means that the health worker watches the patient swallow all her/his drugs. Ensure that drug administration, including streptomycin injections, are properly explained. Use a sample of blister-packs to explain about the drugs that the patient will have to take. Explain that diet and rest have limited impact on outcome of treatment, but that regular drug-taking is essential.

- **How tuberculosis spreads**

  Explain in simple terms that TB can spread when a patient sneezes or coughs. People in close contact with the patient can become infected when they breathe in these germs (tubercle bacilli). Stress the importance of taking all family members exposed to the disease (contacts) and who have symptoms of TB to the closest health facility for screening of TB. In particular, children under 6 years of age should be screened because they are at risk of developing severe forms of the disease. Also explain how to prevent TB from spreading (for example, by covering the mouth when coughing and sneezing and avoiding spitting in public).

- **Looking for symptoms of tuberculosis**

  Describe the following symptoms of TB of the lungs to the patient so that s/he can recognize whether a family member might be a TB suspect:

  - A cough which lasts for 3 or more weeks is the commonest symptom
  - Usually, the person also has one or more of the symptoms listed below:

- Weight loss;
- Tiredness;
- Fever, rise in temperature especially in the evening;
- Night sweats;
- Chest pain;
- Shortness of breath;
- Loss of appetite; and
- Coughing up of blood-stained sputum

In the following example, the Medical Officer is talking to a patient who has just been diagnosed with pulmonary smear-positive TB.

ROLE PLAY

MO: *"Hello, Mrs Khurana. How are you feeling this morning?"*

Patient: *"I am very tired. My chest hurts and I have been coughing."*

MO: *"I am sorry to hear you are not feeling well, but you will get better. Do you know what disease you have?"*

Patient: *"I don't know. I just have cough for one month."*

MO: *"Your sputum examination showed that you have TB germs and suffer from TB of the lungs. However, your disease is curable if you take all the drugs given to you for the recommended time period. Have you ever been treated for TB before?"*

Patient: *"No, I have not been treated for TB before. My brother had TB last year and had to stay in the hospital, but I never had TB. Do I have to stay in the hospital to get better?"*

MO: *"No, only people who are very sick from TB have to stay in the hospital. But you can walk to the health centre. To get better, you need to take all the drugs given to you under the direct observation of a health worker at the health centre for 2 months. You will have to come to the health centre to take 24 doses of medicine during the first two*

months. The health workers are well trained and will watch you swallow your drugs. They will make sure you are getting better.

After 2 months, you will go once a week to the health centre to swallow the first dose of the week and to collect the drugs for the rest of the week. You will swallow drugs thrice a week for 4 months for which you will have to come to the health centre 18 times. In all, you will have to come to the health centre only 42 times during six months."

Patient: *"So, I will have to take drugs for 6 months?"*

MO: *"Yes, you must take the drugs prescribed to you thrice a week for 6 months to get cured. We will check your sputum periodically to see how well you are responding to treatment. If you feel any discomfort after taking medicines, such as nausea or dizziness, tell us at once and we will take care of it. The medicines will turn your urine orange-red in color. It is normal and it will go away, so do not worry about it. Tuberculosis treatment is free. With treatment, your symptoms may disappear and you may feel well. But, you have to be regular with your treatment even after symptoms improve, and complete the whole course to be cured completely. Do you know how TB spreads?"*

Patient: *"No, I do not know how TB spreads."*

MO: *"TB spreads when a person who has TB of the lungs and has not taken drugs to cure it, sneezes or coughs in front of others. Very small germs are released and can be breathed in by someone standing near that person. At this time, there are a few germs. But after some weeks, the inhaled germs reproduce, producing more germs which attack the lungs. If you cover your mouth when you cough or sneeze, and do not spit in front of others, you may prevent TB from spreading. Another way of preventing TB from spreading is to encourage all people with whom you are in close contact and who have symptoms of TB to come to the health centre for a sputum smear examination. This can lead to early diagnosis and treatment. Do you know what the symptoms of TB are?"*

Patient: *"I do not know the symptoms. What are the symptoms of TB?"*

MO: *"The most common symptom of TB is cough for more than 3 weeks. Other symptoms are weight loss, tiredness, fever, night sweats, chest pain, shortness of breath, loss of appetite, and/or coughing up of blood."*

Patient: *"My oldest daughter has been coughing for several weeks. I will make sure she goes to the health centre for examination."*

MO: *"That is very good. Do you have any questions about your disease or your* ***treatment?"***

Patient: *"No, I do not have any questions right now."*

On a continuous basis

There are several things to discuss with the patient about TB after the patient has been in the intensive phase for approximately one week. Then, this information should be repeated to the patient at least once a week during the intensive phase and once a month during the continuation phase. (This is done in privacy or within a group setting. Periodic patient-provider group meetings can be very useful for both patients as well as providers.)

When you meet with the patient, spend the first few minutes checking if s/he remembers what was previously discussed regarding the treatment. Ask the patient questions, such as 'How long will your treatment last?'

Health education topics should be discussed with the patient on a continuous basis. It is important to ask the patient questions throughout this discussion to make sure s/he understands what is being said.

- **Type and colour of prescribed drugs/injection**

  Explain the different types of drugs the patient will be taking. Also, discuss the colours of the drugs so that the patient can identify whether s/he is being given the correct drugs.

- **Amount and frequency of drugs/injection**

  Tell the patient the number of tablets, and dosage of each drug she/he will be taking from the blister pack, how often will be taking them, and for how long.

- **Possible side-effects of drugs/injection.**

  Explain to the patient the following side-effects of the anti-TB drugs s/he is taking. Reassure the patient that the side effects are rare.

  - Skin rashes
  - Skin and/or eyes turn yellow
  - Flu-like symptoms (fever and chills)
  - Pain and swelling of joints, particularly ankles and wrists
  - Difficulty with vision (in patients taking ethambutol)
  - Imbalance (in patients taking streptomycin)
  - Tell the patient that if s/he experiences any of these side-effects, s/he must go to the nearest health facility immediately.

- **Frequency and importance of sputum smear examinations**

  Explain to each pulmonary TB patient that s/he will be required to undergo sputum examinations 3-4 times during the treatment of TB. Tell the importance of bringing up sputum from deep within the lungs for examination by a laboratory technician. The laboratory technician uses a special instrument called a microscope to see whether there are TB germs in the sputum. Tuberculosis germs cannot be seen with the naked eye. If the laboratory technician sees TB germs in the sputum during microscopy after the intensive phase of treatment, the patient is still sick. If the technician does not see TB germs in the sputum during microscopy, the patient is getting better, but s/he must continue to take the drugs.

  Inform the patient the intervals at which s/he will have to get her/his sputum examined. Explain the importance of finding out the results of sputum smear examinations.

  These results can affect the remaining treatment, its duration as well as quantities of drugs. In simple terms, also stress the importance of sputum conversion at the end of 2(3) months and at the end of treatment.

- **What happens if the patient takes only selected drugs**

  Tell the patient that s/he needs to take all her/his prescribed drugs together to be cured. Tell her/him if he does not take all her/his drugs, the germs might produce more germs again. After a while, the germs will be back in large numbers and the patient will become sick again. Explain that during the continuation phase also, the patient must take all her/his drugs for the entire prescribed period because the disease is not yet cured even though the patient might feel better.

During the first week of the intensive phase

In the following example, the patient is classified as a new pulmonary smear-positive case. A nurse is providing health education to the patient after one week of starting treatment. The patient is 35 years old and weighs 52 kilograms.

ROLE PLAY

Nurse: *"Hello, Mr Singh. How are you feeling this morning?"*

Patient: *"I am not feeling very well. I have been coughing and I get night sweats. I am very tired."*

Nurse: *"Well, you will be feeling much better in a week or two. The drugs you are taking are very strong. Do you remember for how long you will be treated?"*

***Patient**: "I think I will come here thrice a week on alternate days for 2 months so that you can give me my drugs"*

***Nurse:** "Yes. We will make sure you are getting better. We will give you one red capsule and 6 white tablets. After 2 months of DOT, you must continue treatment and collect your drugs once a week from the health facility. At the time of weekly collection, you must take the first dose directly observed. Do you remember how long you will continue taking drugs after the initial 2 months of treatment is over?"*

***Patient:** "I do not remember how long I must take the drugs."*

***Nurse**: "After the 2 months of DOT, you will collect the drugs every week for 4 months. Although you might feel better, you must still take all your drugs. Do you have any questions?"*

***Patient:** "I do not have any questions."*

***Nurse:** "Now tell me what type of drugs and how many of them you are given?"*

***Patient:** "I am getting 1 red capsule and 6 white tablets at each visit thrice a week."*

***Nurse:** "That is correct. Rarely, some of these drugs may cause a reaction such as skin rash, yellowness of the skin or eyes, fever, chills, pain and swelling of joints, particularly ankles and wrists, or difficulty in seeing. If you get any of these reactions, tell me or any of the nurses immediately. Do you understand what you need to do if you get any kind of reaction to the drugs?"*

***Patient:** "Yes, I understand that if I have any of the symptoms you mentioned or I feel more ill from the drugs I should tell you or another nurse right away."*

***Nurse:** "Good. Now, you have been diagnosed with tuberculosis of the lungs. You will take strong drugs so you will get better. After 2 months, we will ask you to bring up your sputum and collect it in a container which we will give you so as to find out if you still have TB germs in your lungs. The container will be sent to a laboratory technician who will examine the sputum under a microscope. These germs cannot be seen with the naked eye. Only through the microscope we can see whether the sputum has TB germs. If no germs can be seen through the microscope, the treatment has been effective so far. You will continue your treatment for an additional 4 months, as we have previously discussed. However, if TB germs are seen through the microscope, you will have to continue closely supervised treatment for 1 more month. This is to make sure that the drugs are working and that you get cured. After the additional month, you will receive treatment for another 4 months. In that case, your complete treatment would last for 7 months.*

At the end of 4 months of treatment, you will be asked to bring up your sputum again and collect it in a container. This sputum examination is to make sure you still do not have any TB germs in your lungs. Then, the last time you come to collect the drugs, towards the end of 6 months of treatment, you will bring up sputum one last time into the container. We will check your sputum for the last time. Then we can know whether you have been cured."

Patient: *"What can I do to get rid of the TB germs?"*

Nurse: *"As you know, we give you drugs thrice a week for 2 months. You must swallow all the drugs you are given in front of us. If you do this, you will get rid of most of the TB germs after 2 months. However, after this period you must also take your drugs thrice a week for 4 months even if you feel better. If you do not take the drugs for all 6 months, you might not be cured. If you find it difficult to come to this health facility, you may identify any responsible person in your locality, who is prepared to administer drugs at the time convenient to you. We will educate him/her and provide drug box and duplicate treatment card so that you will not miss the drugs. Do you have any questions?"*

Patient: *"No, I do not have any questions. I will take all my drugs so that I get better."*

Nurse: *"Good. I hope you feel better soon."*

Exercise 2

Perform a role-play on how to communicate with a new smear-positive patient after 2 months of treatment. The patient has come to the health facility with her/his sputum smear examination report, which shows that s/he has become sputum smear-negative at the end of intensive phase.

EXERCISE WORKBOOK E2:
COMPLETION OF TUBERCULOSIS TREATMENT CARDS

Use a calendar for 2003 and 2004. Treatment begins in 2003. Neither diagnosis nor treatment is done on Sundays. Use your own state, district and sub-district names on the Tuberculosis Treatment Card. Be sure to indicate outcome and date on side II of the Tuberculosis Treatment Card.

Remember that you must make up for missed doses. For this exercise, names and addresses of contact persons are not given. In practice, the names and addresses of contact persons must be filled up to aid in retrieving patients who have interrupted treatment. Use the Laboratory Forms for Sputum Examination you completed in Exercise Workbook E1 to complete the Tuberculosis Treatment Cards.

Parvathi Sinha (Patient B) is a 16-year-old female who weighs 41 kg. She has never been treated for tuberculosis before. She has pulmonary and extra-pulmonary (lymph node) tuberculosis. She started treatment on 8 September. The first 24 doses were all observed as scheduled except for dose 21 which was given one day late. On follow-up at two months, she is smear-negative (29 October, Lab No. 612), weighing 45 kg. She then defaulted on 17 November.

Lakshmi Kumari (Patient C) is a 46-year-old woman who weighs 62 kg. She has never been treated for tuberculosis before. She started treatment on 16 September and her sputum is negative at the end of 2 months (6 November, Lab No. 623, 64 kg), 4 months (30 December, Lab No. 720 66 kg) and 6 months (3 March, Lab No. 125, 70 kg). She takes every dose as prescribed, under direct observation thrice a week in the intensive phase and once a week under direct observation in the continuation phase.

Lakshmi Pati Rao (Patient D) is a 49-year-old man who weighs 46 kg. He has had cough for years. When asked, he reports that he had received treatment for 'pneumonia' several times in the past. He remembers receiving shots once for a few months, and taking a medicine which made his urine turn orange. He recalls that these medicines helped him feel better. He has not been on treatment since the last 3 months. He starts treatment on 16 September. Doses 3, 9, 15 and 30 were missed entirely (count from doses actually given). His sputum was positive (2+) at the end of 3 months (11 December, Lab No. 675, 45 kg). Doses 44 and 47 were taken one day late. His sputum was positive (2+) at the end of 4 months (15 January, Lab No. 31; 43 kg).

Sputum was negative at the end of 6 months (10 March, Lab No 139; 43 kg) and positive (3+) at the end of 9 months (23 June, Lab No. 348; 40 kg). The patient attended all weekly collections except the 12th and 14th, which he missed entirely. When should his sputum be sent for culture and sensitivity testing, if available?

Kailash Nath (Patient F) is a 35-year-old man who weighs 39 kg. He has never been treated for tuberculosis before. He starts treatment on 16 September. His drugs are administered under direct observation in the intensive phase, but doses 12 and 16 were given one day late. His sputum is positive (1+) at the end of 2 months (4 November, Lab No. 619, 42 kg). What is the correct treatment? Dose 30 was given one day late. His sputum is negative at the end of 3 months (2 December, Lab No. 657). He received all weekly collections in the continuation phase of treatment, except the fourth week dose which he took one day late. His sputum is negative at the end of 5 months (27 January, Lab No. 55, 45 kg) and 7 months (7 April, Lab No. 195, 50 kg).

Ghanshyam Singh (Patient I) is a 16-year-old male with extra-pulmonary tuberculosis of the knee. He has never been treated for tuberculosis previously. He weighs 38 kg. Treatment began on 4 September. He was directly observed for all doses as prescribed. Orthopedic follow-up examination was done and no further recommendations for orthopaedic follow-up were given.

Lallan Prasad Parmar (Patient L) is a 51-year-old man. He was treated with short-course chemotherapy for smear-positive TB at this centre for 8 months one year ago and had completed the treatment prior to the implementation of RNTCP. He now has cough and fever for the past month. One sputum sample out of three is positive. X-ray shows right upper lobe cavity. He begins treatment on 17 September. His initial weight was 38 kg. He did not take doses 31 and 34 as scheduled, but these were made up on the next day. His sputum smear was negative at the end of 3 months (5 December, Lab No. 663, 40 kg). After 5 weeks of the continuation phase he is transferred to District Y.

Kiran Kumar(Patient O) is a 37 year old man with three negative sputum smear examinations, living at 15, Gulmohar Park, whose cough did not improve after a 10 day course of co-trimoxazole. The sputum examination was repeated and again yielded negative results for three samples. Chest X-ray showed infiltrates in the left lower and right upper lung fields and it was decided that he should receive a full course of anti-TB treatment. He was not treated for Tuberculosis before. His initial weight was 45 Kgs. He began treatment on 23rd September. He missed doses 12 and 18 entirely. His sputum smear is negative at the end of intensive phase (18th November, lab no. 638, 48 Kg) and 6 months (13^{th} March, Lab No. 146, 50 Kg). No collections were missed during the continuation phase.

PHI LEVEL—MONTHLY REPORT ON PROGRAMME MANAGEMENT, LOGISTICS AND MICROSCOPY

All Peripheral Health Institutions (PHIs) are required to complete this report (see format of monthly PHI Report on page 179. However, the latter section of the report is meant only for the Designated Microscopy Centres. This report contains information on drug position, staff position and their training status, referral activities, microscopy activities, treatment initiation, consumables position and status of microscopes at the PHI level. This report is to be prepared after physical verification of stock on the last working day of the month by the Medical Officer of the PHI, with the assistance of her/his staff. The report has to be sent to the CDHO/CDMO, with a copy to the TB Unit, on or before the 5th of the next month. Thereafter, the DTO can collect copies of these reports from the office of the CDHO/CDMO for close monitoring of microscopy and logistics in the district on a monthly basis. The copies at the TU level can be used for monitoring as well as preparation of Quarterly Reports for the TU.

Medications

The first section of this report is on Medications. It tallies stock at the beginning of the month, stock received during the month, stock consumed during the month, and stock on the last day of the month. From these figures and the expected caseload (based on the patients started on treatment in the month), the requirements of each item are calculated for the next month.

Example:

PHI 237 is a designated microscopy centre. In the reporting month, 3 patients were started on CAT I treatment, one patient was started on CAT II treatment, and 3 patients were started on CAT III treatment. The medications part of the monthly report for PHI 237 is as given below.

Medications

Item	Stock on first day of month (a)	Stock received during month (b)	Patients started on treatment during month (c)	Stock on last day of month (d) =a+b-c	Quantity requested (e) = (cx2)-d
Category I PWB	4	2	3	3	3
Category II PWB	1	1	1	1	1
Category III PWB	3	2	3	2	4

(PWB: Patient-wise Box)

At the PHI level, a reserve drug stock of one month should be maintained. The monthly requirement of drugs for the next month is estimated based on the number of patients started on treatment in the reporting month and by ensuring a reserve stock of one month at the PHI. The report on "prolongation pouches" and individual drugs are also prepared in the same manner.

The 'stock on first day of month' in the current month's report should always match with the 'stock on last day of month' in the previous month's report.

Staff Position and Training

This section reports information on staff position: sanctioned number, staff in position and number of them who have been trained in RNTCP. Since staff turnover is common, this information is important for the tuberculosis control managers to plan training of new staff and, in the case of vacancies, redeployment of staff, if necessary.

For example the staff position and training section of a particular PHI is as under:

Category of staff	Sanctioned	In position	Trained in RNTCP
Medical Officer	3	2	2
Laboratory Technician	1	1	1
Pharmacist	1	1	1
Multi-purpose Health Worker	8	6	0

From this information, it can be seen that in addition to filling up the vacant posts, there is a need to train all multi-purpose health workers at this PHI.

Referral activities

The number of new adult out-patients visiting the PHI during the month is to be reported here. Information on the number of chest symptomatics referred for sputum examination is also reported in this section. A patient making repeated visits for the same ailment should be counted only once. All patients less than or equal to 14 years of age are not treated as adults for the purpose of reporting. This section of the report enables you to determine whether a minimum of 2% of new adult outpatients are being referred for sputum examination.

Example

An example of PHI 237, is given below:

Referral Activities (To be filled in by PHIs with DMCs as well as PHIs without DMCs, from OPD Register)

a.	Number of new adult outpatient visits	2800
b.	Out of (a), number of chest symptomatic patients referred for sputum examination	60

Number of chest symptomatic patients referred for sputum examination should be more than 2% of the number of new adult out-patients. If the "referral for diagnosis" is less than 2%, medical and paramedical workers of the PHI should be encouraged to refer all patients who have cough for more than 3 weeks to the nearest Designated Microscopy Centre for sputum microcopy for diagnosis.

Microscopy Activities
This section is essential to evaluate the microscopy activities i.e., the number of patients whose sputum was examined and the number of smear-positive patients diagnosed.

Example
An example, using PHI 237, is given below:

Microscopy Activities (To be filled in only by DMCs, from Lab Register)

c.	Number of TB suspects whose sputum was examined for diagnosis in the Designated Microscopy Centre	60
d.	Out of (c), number of sputum smear-positive patients diagnosed	07
e.	Number of TB suspects subjected to repeat sputum examination For diagnosis	05
f.	Out of (e), number of sputum smear-positive patients diagnosed	01
g.	Total number of sputum smear-positive patients diagnosed (d+f)	08

Number of sputum smear-positive patients would be around 10% of the number of chest symptomatic patients whose sputum was examined for diagnosis.

Treatment Initiation (To be filled in only by DMCs, from Lab Register and Referral for Treatment Register)

Information on patients started on treatment is an important section of the monthly report. This is the section in which information is collected on sputum positive patients

being put on RNTCP DOTS and RNTCP Non-DOTS treatment. It also provides information regarding sputum positive patients who were referred for treatment outside the TU. A Referral for Treatment register should be maintained in big hospitals and Medical colleges where large numbers of cases are expected to be diagnosed and referred. The other DMCs which refer sputum positive patients for treatment to other PHIs need to preserve a copy of the referral for treatment form. Patients should be referred to PHIs that are close to their homes for treatment.

The DTO will ensure through his/her TU level staff, that all patients referred between TUs within the district are put on treatment.

Example:
An example, again using PHI 237, is given below:

Treatment Initiation (To be filled in by DMC from Lab Register and Referral for Treatment Register)

h.	Of the smear-positive patients diagnosed (g), number put on DOTS	05
i.	Of the smear-positive patients diagnosed (g), number put on RNTCP Non-DOTS (ND1)	01
j.	Of the smear-positive patients diagnosed (g), number referred for treatment to other TUs within the district	01
k.	Of the smear-positive patients diagnosed (g), number referred for treatment outside the district	00

Of all the smear-positive patients diagnosed in the DMCs, some may start their treatment from some other PHIs in the same TU. The information on whether such patients have been started on treatment should be collected either during regular meetings in the area or from the STS/STLS of the TU when they supervise the PHIs.

Consumables
Laboratory consumables will be requested in the same manner as medications, using the monthly report. Reagents should be prepared at the District or TU level on a monthly basis. TUs should, ensure supply of consumables to the designated microscopy centres in the TU area as per their requirements. Laboratory Forms for Sputum Examinations are supplied to all PHIs in the district. The sputum containers are supplied to the DMCs through the TU to enable collection of sputum samples from TB suspects for diagnosis and from patients under treatment for follow-up sputum examination. Those PHIs which are functioning as sputum collection centres will also be supplied with sputum containers and Lab Forms by the TUs. These PHIs will also have to report information regarding sputum containers in monthly PHI reports.

Microscopes

Every month, each DMC reports on the condition of its microscope(s). If a microscope is not working, it should be repaired promptly. If it is under warranty, the supplier must do this free of charge. If the warranty has expired, immediate efforts should be made to get the repairs done through the agency with which the Annual Maintenance Contract has been signed. Such agencies are appointed either by the DTCS or STCS. In the absence of an AMC, the repairs should be done through a reputed agency. If there is no functional microscope at any DMC temporarily, interim arrangements should be made for sputum collection and transport to the nearest functional DMC.

Name and Signature

The name and signature of the reporting officer is given. This should generally be the MO who has been designated as in-charge of tuberculosis work at the PHI.

POINTS TO REMEMBER

- Eliciting history of previous anti-tuberculosis treatment is essential for correct categorization of the patient
- Proper categorization is essential for achieving cure
- A suitable DOT provider and DOT centre should be selected in consultation with the patient
- Ensure that treatment is being directly observed for all doses of the intensive phase and the first of the thrice-weekly dose in the continuation phase
- Ensure that the Tuberculosis Treatment Card is accurately filled, complete, and up-to-date
- Initial counseling (at the health facility and at patient's home) is important to achieve treatment compliance
- Patients missing doses should be traced and put back on treatment within one day in the intensive phase and within one week in the continuation phase
- Streptomycin injections, where required, should be given after the oral drugs are administered
- It is preferable to use disposable syringes and needles to administer streptomycin
- Always give chemoprophylaxis to children of smear-positive patients who are below 6 years of age

- Breast feeding should continue regardless of the mother's TB status
- Ensure that people living with HIV/AIDS who have TB disease are always put on RNTCP regimens under DOT
- Category II failure patients ("chronic cases") are not treated under RNTCP and should be referred to tertiary hospitals for assessment and treatment
- Category II failure patients may be sensitive to first-line of drugs and hence should never be labeled as multi-drug resistant cases without laboratory evidence

ANNEXURE I: MANAGEMENT OF PEDIATRIC TB UNDER RNTCP

INTRODUCTION

Childhood TB is a reflection of the prevalence of sputum smear-positive pulmonary tuberculosis (PTB) and the extent of transmission of TB infection in the community. Children suffer from more serious forms of TB and are more likely to die if not treated properly. It is estimated that globally about 1.5 million new cases and 130,000 deaths occur annually due to TB amongst children. Reliable data on disease incidence and prevalence is however not available due to the difficulties in diagnosis of pediatric TB under field conditions.

Diagnosis

TB should be suspected among children presenting with fever and / or cough for more than 3 weeks, with or without weight loss or no weight gain; and history of contact with a suspected or diagnosed case of active TB disease within the last 2 years. Diagnosis should be based on a combination of clinical presentation, sputum examination wherever possible, Chest X ray (PA view), Mantoux test (1 TU PPD RT23 with Tween 80, positive if induration >10mm after 48-72 hours) and history of contact. Diagnosis should be made by a Medical Officer and the existing RNTCP case definitions be used for all cases diagnosed. PPD would be supplied by CTD to district headquarters. See algorithm 1 for the diagnosis of pediatric TB.

Children showing neurological symptoms like irritability, refusal to feed, headache, vomiting or altered sensorium may be suspected to have TB meningitis.

Use of currently available scoring systems is not recommended for the diagnosis of TB among children. Where diagnostic difficulties are faced, the child should be referred to a pediatrician for further management.

Treatment of Pediatric TB

DOTS is the recommended strategy for treatment of TB and all pediatric TB patients should be registered under RNTCP. Intermittent short course chemotherapy given under direct observation should be used in children, as in adults. (Table 1)

Table 1: RNTCP treatment categories and regimens for children

Treatment Category	Type of Patients	Treatment Regimen***	
		IP	CP
Category I	New sputum smear-positive PTB New sputum smear-negative PTB, seriously ill* New extra-PTB, seriously ill*	$2H_3R_3Z_3E_3$***	$4H_3R_3$
Category II	Sputum smear-positive relapse Sputum smear-positive treatment failure Sputum smear-positive treatment after default	$2H_3R_3Z_3E_3S_3$ + $1H_3R_3Z_3E_3$	$5H_3R_3E_3$
Category III	New sputum smear-negative, not seriously ill** New extra-PTB, not seriously ill**	$2H_3R_3Z_3$	$4H_3R_3$

* *In children, seriously ill sputum smear-negative PTB includes all forms of sputum smear-negative PTB other than primary complex. Seriously ill EPTB includes TB meningitis (TBM), disseminated TB, TB pericarditis, TB peritonitis and intestinal TB, bilateral extensive pleurisy, spinal TB with or without neurological complications, genito-urinary TB, and bone and joint TB.*

** *Not seriously ill sputum smear-negative PTB includes primary complex. Not seriously ill EPTB includes lymph node TB and unilateral pleural effusion.*

*** *Prefix indicates month and subscript indicates thrice weekly.*

In patients with TBM on Category I treatment, the four drugs used during the intensive phase should be HRZS (instead of HRZE). Continuation phase of treatment in TBM and spinal TB with neurological complications should be given for 6 - 7 months, thus extending the total duration of treatment to 8 - 9 months. Steroids should be used initially in hospitalised cases of TBM and TB pericarditis and reduced gradually over 6 - 8 weeks.

In all instances, before starting a child on Category II treatment, s/he should be examined by a Pediatrician or TB expert, wherever available.

As recommended by WHO, and in view of the growing evidence that the use of Ethambutol in young children is safe, Ethambutol is to be used as per RNTCP regimen for all age groups.

To assist in calculating required dosages and administration of anti-TB drugs for children, the medication would be made available in the form of patient wise-boxes, linked to the child's weight. The recommended dosages for children, in mg/kg, are given in Table 2.

Table 2: Suggested pediatric dosages for intermittent therapy

Drugs	Dosage (Thrice a week)
Isoniazid	10–15 mg/kg
Rifampicin	10 mg/kg
Pyrazinamide	30-35 mg/kg
Ethambutol	30 mg/kg
Streptomycin	15 mg/kg

For monitoring treatment, follow-up sputum examinations are to be performed with the same frequency as in adults. Clinical or symptomatic improvement is to be assessed at the end of the intensive phase of treatment and at the end of treatment. Improvement should be judged by absence of fever or cough, a decrease in the size of lymph node(s), weight gain, etc. Radiological improvement is to be assessed by Chest X-ray examination in all smear-negative pulmonary TB cases at the end of treatment. (Algorithm 2).

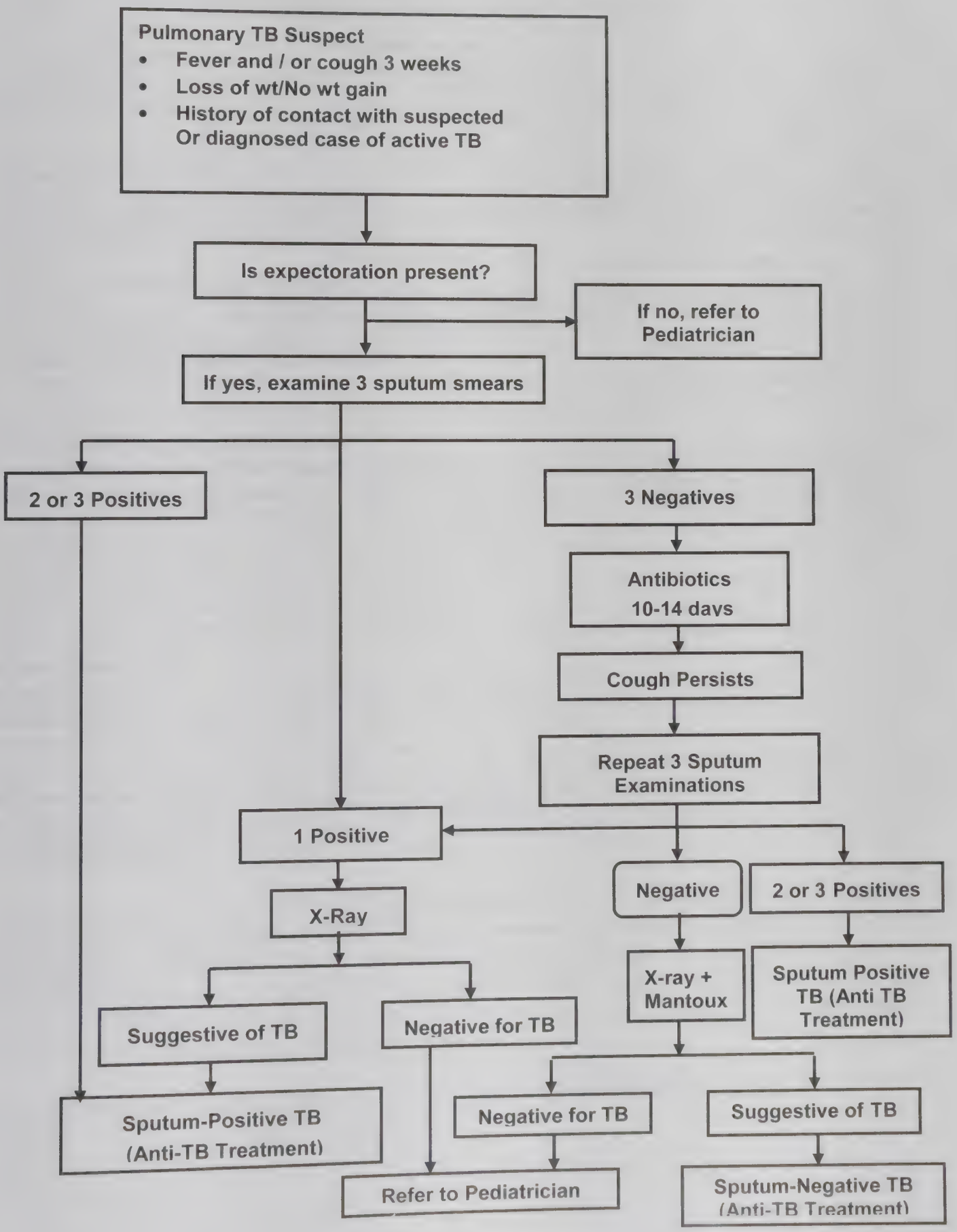
- **DOTS is the recommended strategy for treatment in adults as well as children**
- **All pediatric TB patients should be registered under RNTCP**

3. Chemoprophylaxis

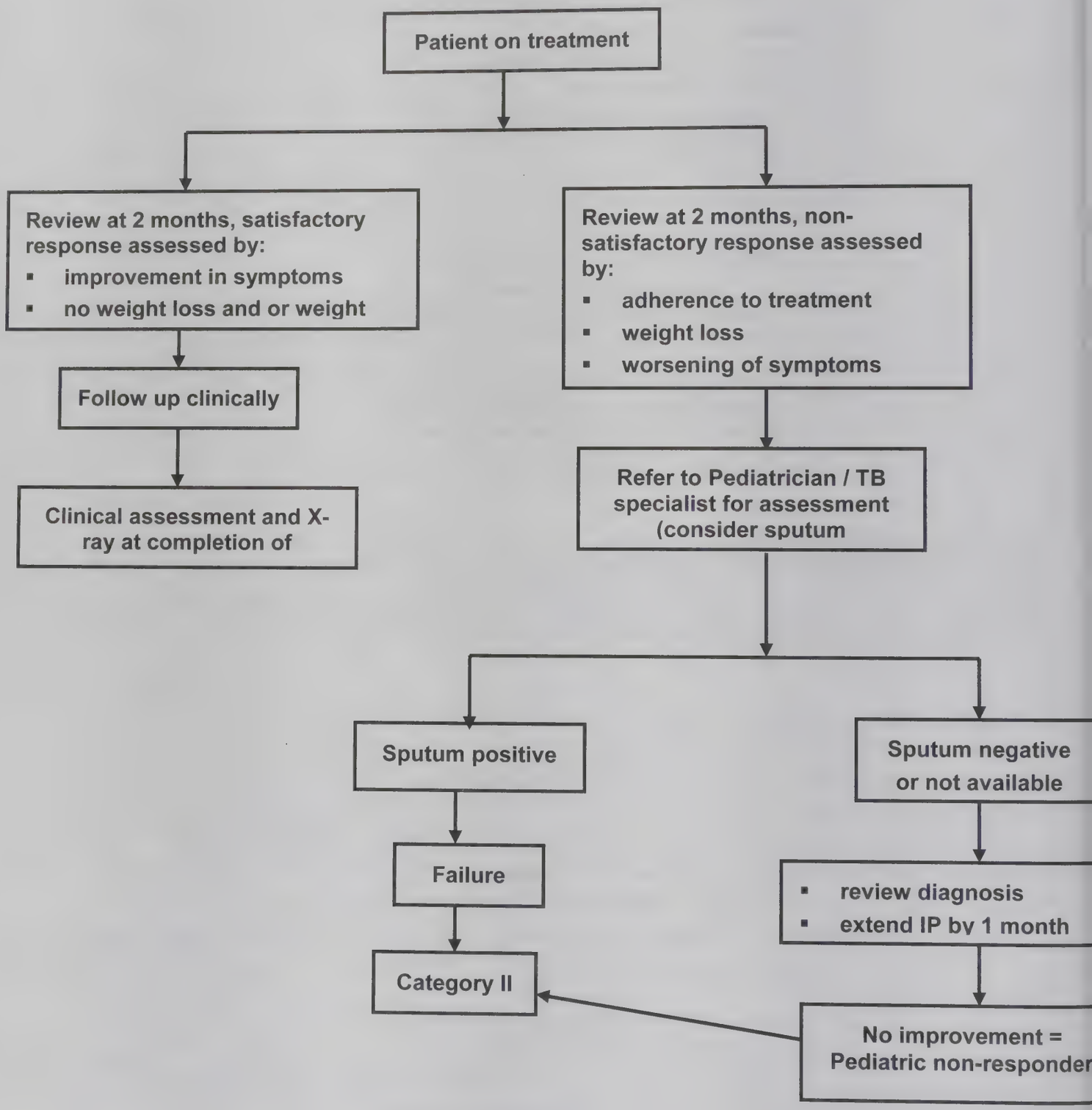
Recent infection with tubercle bacilli is one of the risk factors for disease development. The younger the child, the higher is the risk of breakdown of infection into disease. Therefore, household contacts of smear-positive TB cases, especially those below 6 years of age, must be screened for symptoms of tuberculosis. In case of symptoms being present, the diagnostic algorithm for pediatric TB should be followed and the child should be given a full course of anti TB treatment if s/he is diagnosed as a TB case. For asymptomatic children and those who are not found to be suffering from TB, chemoprophylaxis with isoniazid (5 mg per kg body wt) should be administered daily for a period of six months. This is regardless of the BCG vaccination status.

To ensure that proper preventive chemotherapy is given to children, enquire (or have the health workers enquire) from all smear-positive tuberculosis patients under treatment if they have children under 6 years of age. Explain to them how children can acquire the infection which may later develop into tuberculosis. Make sure that the children are brought to a health unit for screening.

Algorithm 1: Diagnostic Algorithm For Pediatric Pulmonary TB



Algorithm 2: for clinical monitoring



ANNEXURE II: TREATMENT OF TB IN HIV-INFECTED PATIENTS

Anti-TB treatment is the same for HIV-infected persons as it is for HIV-negative TB patients. Hence they should be treated with RNTCP regimens under DOTS strategy.

All new TB cases known to be HIV positive should be treated with Category I regimen as they are taken as seriously ill. The re-treatment cases are to be treated with Category II regimen. RNTCP regimens, if supervised properly, are as effective in HIV positive as in HIV negative patients.

It is important to maintain confidentiality regarding HIV-positive status of TB patients under anti-TB treatment, in order to prevent stigmatization and discrimination against the patient. The HIV status of patients under TB treatment should be voluntarily shared by the patient with the treating physician for the purpose of taking clinical decisions like categorization for treatment of TB, treatment of other opportunistic infections and provision of ART. However, the national policy is not to test all TB patients for HIV. Only those TB patients who have other HIV-associated opportunistic infections, or report risk behavior for HIV, may be referred for voluntary counseling and testing to the nearest Voluntary Counselling and Testing Centre (VCTC). The HIV-positive status should not be disclosed to any other staff involved in RNTCP. In addition, the HIV-positive status should not be mentioned in any RNTCP records.

Adverse effects of anti-TB drugs could be more common in HIV-positive than in HIV-negative TB patients.

How effective is DOTS in TB-HIV?

Directly observed treatment with effective short-course treatment regimen is even more important for HIV-positive TB patients. Self-administration of treatment is associated with higher case fatality rates. Hence a DOT strategy that ensures adherence to therapy should be used for all HIV-positive TB patients.

The relapse rate of TB in HIV-positive TB patients who complete directly observed treatment with short-course regimen is low. However, it is higher when compared with HIV-negative TB patients. This increased rate of relapse of TB in HIV-positive individuals is more likely to be due to re-infections rather than true relapse. However, treatment interruptions due to drug reactions and inter-current opportunistic infections could also lead to an increased risk of relapse of TB.

Failure to use DOTS in the face of HIV can lead to a rapid spread of TB.

Anti tuberculosis therapy and antiretroviral therapy (ART)
The antiretroviral drugs, which are used in HIV-positive patients, are effective in slowing down the action of the virus and prolonging life. These drugs are grouped as nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, nucleotide reverse transcriptase inhibitors, protease inhibitors and fusion inhibitors.

Protease inhibitors and non-nucleoside reverse transcriptase inhibitors may inhibit or induce cytochrome P-450 isoenzymes and thus alter the serum concentration of Rifamycins. Rifamycins induce cytochrome P-450 and substantially decrease blood levels of these antiretroviral drugs. Dose adjustments for Nevirapine co-administered with Rifampicin has not been established. Hence, co-administration of Rifampicin with any of the protease inhibitors (Ritonavir, Indinavir, Nelfinavir) or non-nucleoside reverse transcriptase inhibitors (Nevirapine) should be avoided.

If a protease inhibitor or non-nucleoside reverse transcriptase inhibitor is to be started after giving Rifampicin, then at least two weeks should elapse after the last dose of Rifampicin. This time gap is necessary for reduction of the enzyme inducing activity of Rifampicin prior to commencement of antiretroviral drugs. People with TB/HIV should complete their TB therapy prior to beginning ARV treatment unless there is a high risk of HIV disease progression and death during the period of TB treatment (i.e., a CD4 count <200/mm3 or the presence of disseminated TB).

The current recommendations on ART are to use a triple drug combination. A combination of, (Zidovudine or Stavudine) plus Lamivudine plus (Abacavir or Efavirenz or Nevirapine or Saquinavir) is usually used.

Anti-tuberculosis Treatment for patients on ART
Treatment of TB patients co-infected with HIV cannot be envisaged without Rifampicin. In TB patients co-infected with HIV, treatment should be first administered for TB under the DOTS strategy and ART should be started after completion of TB treatment. In patients with very low CD4 counts requiring concomitant administration of ART and anti-TB treatment the ARV regimen should be modified by replacing Nevirapine with Efavirenz. On completion of TB treatment such patients can be switched back to Nevirapine.

ANNEXURE III: EXTRAPULMONARY TB

Extra-pulmonary TB comprises of about 10% to15 % of all TB cases in our country. Among them, 75% have lymph nodal or pleural TB.

The precise diagnosis of some of the severe forms is a challenge to physicians as they present a symptom complex with extraordinary diversity. A High index of suspicion is a pre-requisite for an early diagnosis as 20% to 40% have been reported to be diagnosed only on postmortem examination. Delay in diagnosis can be fatal or result in life threatening sequelae in meningeal TB. Intermittent short course chemotherapy regimens of 6-9 months are recommended internationally for all forms of extra-pulmonary TB. In cases of TBM, initial hospitalization is recommended. In TBM, ethambutol should be replaced by streptomycin in the intensive phase and continuation phase of the treatment is for 6-7 months. Adjunctive steroids may be useful in pericardial and meningeal TB.

Management of TB lymphadenitis

Lymph node TB usually presents as slowly progressive, painless enlargement of the lymph nodes of neck, sometimes of axilla or groin. Cervical lymph node TB is the most common manifestation of extra-pulmonary form of TB. Lymph node involvement of more than one group is common. Individual nodes are firm and discrete though matting of nodes may occur and may progress to abscess and sinus formation if left untreated. Tubercular abscess is also called “cold abscess” since inflammation is uncommon.

The commonest form of extra-pulmonary TB is TB Lymphadenitis

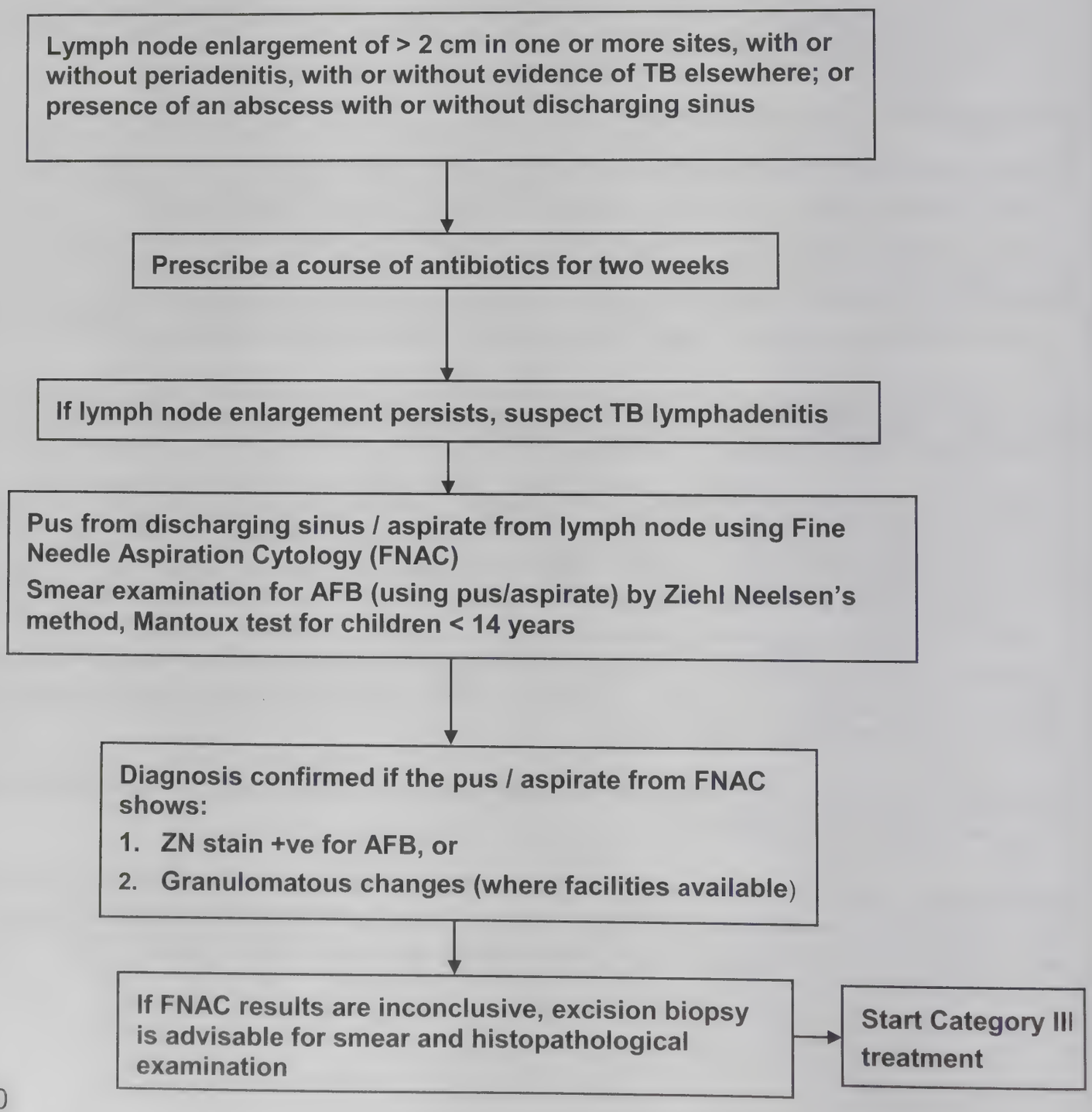
In addition, constitutional symptoms like fever, malaise, weight loss, anorexia, etc. may be present but not invariably. This form of TB is more common in children and adults who are less than 30 years of age. Diagnosis based on clinical findings alone can lead to over-diagnosis in a high proportion of cases. Therefore, attempt should always be made to confirm diagnosis by undertaking fine needle aspiration cytology (FNAC). This procedure can be undertaken wherever facilities are available. Refer to the diagnostic algorithm for details. In addition, sometimes chest radiograph may reveal mediastinal widening suggestive of hilar adenitis.

Intermittent 6-month SCC regimen has been proven to be very effective in the treatment of superficial TB lymphadenitis.

Paradoxical reactions in the form of persistence or enlargement of existing nodes or appearance of new nodes may occur in about one fourth of cases during treatment as well as after completing treatment, and sometimes even a few months later. These

reactions do not indicate treatment failure and probably represent an immune response to the release of mycobacterial products caused by the rapid bactericidal activity of the drug regimens. Therefore, extension or modification of treatment is not warranted as they usually regress spontaneously. Residual lymphadenopathy, after treatment completion has also been reported in about one third of patients. Studies have shown that re-treatment is required only if residual lymph node biopsy is bacteriologically confirmed as positive by culture for Mycobacterium tuberculosis. As culture facilities are not available everywhere, FNAC may be resorted to. However the granulomatous changes may persist for a long time even after adequate treatment. Hence the decision to start re-treatment can not be based on histo-pathological proof alone. The relapse rates after SCC are reported to be quite low.

Diagnostic algorithm for TB lymphadenitis



Management of Pleural TB

Patients presenting with chest pain with or without difficulty in breathing for more than two weeks should be referred for chest radiograph. Constitutional symptoms like fever, anorexia, loss of appetite may be present but not invariably. If chest X-ray shows blunting of costophrenic angle, suggestive of pleural effusion, patient will be started on Category III. Pleural aspiration for biochemical, cytological and smear examination by Z-N stain is an additional aid in confirming the diagnosis. Pleural fluid is generally an exudate with mainly lymphocytes and few mesothelial cells. Pleural biopsy is confirmatory in a high proportion of patients. Massive and bilateral effusions are classified as seriously ill forms of extra-pulmonary TB and treated with Category I regimen.

ANNEXURE IV: MULTI-DRUG RESISTANT TUBERCULOSIS AND DOTS PLUS

Multi-drug resistant TB (MDR-TB) is a specific form of drug resistant TB due to bacilli resistant to at least Isoniazid and Rifampicin, with or without resistance to other anti TB drugs. Diagnosis of MDR-TB is a laboratory diagnosis (from a quality assured laboratory) and not a clinical diagnosis. Drug resistance arises due to improper use of anti-tuberculosis drugs during the treatment of tuberculosis patients. This improper use includes:

- Administration of inadequate treatment regimens by various health care providers.
- Wrong treatment categorization by failing to elicit the history of previous anti TB treatment
- Poor treatment management, when the treatment is not directly observed.
- Inability to educate patient to take complete and regular treatment.

Essentially, drug resistance arises in areas with poorly managed TB control programmes, which is often a reflection of the lack or improper implementation of DOTS in such areas. Regular chemotherapy under DOTS strategy can prevent the emergence of MDR-TB

Extent of MDR TB in India

MDR-TB is a concern for tuberculosis control in many countries. Currently the prevalence of MDR-TB among new smear-positive cases is relatively low in the country. Studies carried out in six districts during 1999-2002 as per the WHO guidelines on drug resistance surveillance, showed that 0.5% to 3% of new cases were found to harbor multi-drug resistance bacilli. Studies amongst previously treated patients showed MDR levels of 12%.

Drug resistance surveillance

In order to monitor the level of drug resistance in the country, drug resistance surveillance is being conducted among both new and previously treated cases in selected states in a phased manner using the national and state level RNTCP laboratory network. The laboratory network consists of 3 designated National Reference Laboratories (NRL), namely, The Tuberculosis Research Centre, Chennai, The National Tuberculosis Institute, Bangalore, and LRS institute of Tuberculosis and Respiratory diseases, New Delhi. State TB Demonstration Centre (STDC) of the respective states are designated as Intermediate Reference Laboratories (IRLs). RNTCP microscopy

centers in each district are assigned the role of identification and enrolment of smear-positive cases for the survey. IRLs perform culture and drug susceptibility tests and NRLs provide technical support. TRC, which is also a WHO Supra-national Reference Laboratory (SRL), will also be responsible for quality assurance.

Prevention of MDR-TB

The management of MDR-TB being very complex, and its occurrence must be prevented by effective implementation of the DOTS strategy.

Proper categorization of patients by medical officer for treatment, by eliciting history of previous treatment, is very important. The diagnosed patients should be explained / educated, why it is essential to know about previous anti-TB treatment and to take drugs under direct observation. Similarly, DOT Providers should be educated and convinced about the importance of directly observed treatment (DOT). DOTS has been documented to not only prevent the emergence of multi drug resistance but also to decrease its prevalence in the community.

Prevention of MDR-TB is given priority under RNTCP rather than its treatment

Management of MDR-TB

The most important cause of treatment failure is the inability to administer complete and regular treatment and not due to drug resistant bacilli. However, TB cases continuing to be smear-positive at the end of 4 months or later of the intensive phase of a CAT II treatment under RNTCP may be suspected of having MDR TB. Only these patients should be sent for culture and sensitivity testing of sputum to a quality assured culture and drug susceptibility testing laboratory. STDCs are being strengthened to provide these facilities in each state. Diagnosed cases of MDR-TB should be referred to and treated only at a specialized centre. Treatment of MDR-TB requires prolonged chemotherapy, which is very expensive and toxic. The treatment must be given for a period of 18-24 months. Moreover, the chances of treatment success are low.

In 1998, WHO and several partners around the world conceived DOTS-Plus and a working group was established in 1999. DOTS-Plus is a comprehensive management strategy that includes the five components of DOTS strategy. It takes into account specific issues, such as the use of second-line anti-TB drugs, that need to be addressed in areas where there is high prevalence of MDR-TB. DOTS-Plus works as a supplement to the standard DOTS strategy, to address both drug susceptible and MDR-TB in areas with significant levels of MDR-TB. Having a successful DOTS based TB control programme in place with a default rate of <5% and availability of an accredited mycobacteriology laboratory in the state, is a prerequisite for considering DOTS-Plus in an area.

ANNEXURE V: INFECTION CONTROL UNDER RNTCP

There is the risk of transmission of tuberculosis infection occurring in health care facilities when patients remain undiagnosed and untreated for tuberculosis. This may be curtailed by early diagnosis and immediate initiation and adherence to RNTCP treatment regimens. This prompt and timely action will make infectious TB patients rapidly non-infectious.

It is now mandatory that any Infection Control plan of the facility should include infection control for TB and TB/ HIV. Broadly, infection control needs to be addressed at three different levels: administrative, environmental and personal.

Administrative control normally relies on the extent of complete implementation of RNTCP diagnostic and treatment guidelines in the health care facility. TB infection control plan includes the following:

- Giving priority for patients with cough for clinical and laboratory investigations for early detection of smear-positive pulmonary tuberculosis patients
- Reducing delay in starting appropriate RNTCP treatment once diagnosed
- Avoiding unnecessary admission for inpatient care
- Assessment of health care workers training needs requirements under RNTCP

Sputum collection should ideally be done outside the facility and away from the people. It should not be done in closed areas such as toilets and in ill-ventilated rooms. Processing specimens for smear microscopy (after sputum collection) has not been documented to cause any increased risk to laboratory personnel. However, TB suspects amongst health care workers should be subjected to screening procedures.

Second priority is **environmental control**, which is used to reduce the generation and concentration of droplet nuclei in the air in high-risk areas. High-risk areas that increase transmission include exposure in relatively small, enclosed rooms in health facilities, which lack adequate cross ventilation in the form of open windows and doors to "clean" the environment through dilution or removal of infectious droplet nuclei. Hence, the TB IC plan should also include educating the patients regarding cough hygiene (covering the face while coughing and avoiding indiscriminate spitting), frequent identification of risk areas within the facility and providing good cross-ventilation to the area.

Wearing of surgical masks made of cotton wool/ gauze/ paper for **personal protection** does not protect the person who is wearing the mask from inhaling the droplet aerosols and hence is not recommended as a means to prevent hospital infection. As mentioned

above, early identification and prompt initiation of RNTCP treatment under direct observation would protect all health care workers from hospital TB infection.

The key to reducing the risk of tuberculosis transmission at health facilities is early diagnosis and prompt initiation of RNTCP treatment regimens until cure. Infectious TB patients become rapidly non-infectious once they are started on directly observed treatment under RNTCP.

All health care workers working at the district level should receive onsite training at least once in two-years regarding the basic concepts of M. tuberculosis transmission and pathogenesis. The training should include the following: Signs and symptoms of TB, increased risk of TB disease in persons who have HIV infection and other immunosuppressive conditions and infection with M. tuberculosis.

An **Infection control** plan for TB-HIV may include precautions to be observed for HIV, in addition to that observed for TB, especially when streptomycin injections are being provided. The risk of acquiring HIV following percutaneous exposure (needle stick/ needle prick with inoculation) from an HIV-positive source is extremely low: 0.25- 0.3%. This is because the concentration of HIV in peripheral blood is extremely low (10^4 infectious virions /ml). On the other hand, the risk of acquiring hepatitis virus (HBV) following similar exposure ranges from 9-30% because the concentration of HBV in blood is high (>10,000,000 infectious doses /ml). The chance of acquiring Hepatitis C is approximately 3-10%. Disposable/ adequately sterilized needles and syringes should be used for streptomycin injection. Following streptomycin injection needles should be destroyed using needle cutters/ destroyers wherever available. Needles and syringes should be disposed using prevailing hospital waste management system.

Health care workers can effectively prevent infections acquired through contaminated blood by the adoption of "Universal Precautions" or "Bio-safety Precautions".

Bio-Medical Waste Management under RNTCP by PHIs:

The Government of India (GoI) under its Environment Protection Act (1986), passed the Biomedical Waste (Management and Handling) Rules in 1998 and a subsequent amendment followed in 2000. The rules form the legal framework for the collection, segregation, transportation, treatment and disposal of biomedical waste throughout the country. The State Pollution Control Boards (SPCBs) in the states and the Pollution Control Committees (PCCs) in the Union Territories are monitoring the compliance to the rules in the respective states.

The RNTCP is integrated into the general health system of the states. Waste management is a component of overall facility management of the respective state health system institutions where RNTCP centres are located. Accordingly, **the waste**

generated by RNTCP should not be viewed in isolation, but is to be integrated in the broad framework of the peripheral institutions' waste management practices. The peripheral health institutions would be responsible for disposal of the wastes and reporting to their respective PCBs.

Types of wastes generated by the RNTCP

- Human/biological waste (sputum);
- Sharp waste (needles, glass slides etc.);
- Used blister packs, drug packaging material;
- Plastic waste (waste generated from disposable syringes, cups and glasses); and
- Laboratory and general waste such as liquid waste, broomsticks, and paper waste; and
- Construction waste (waste generated from civil work activities).

Waste Management for RNTCP

Waste generated under RNTCP will be discarded with the overall waste of the health facility in which services under RNTCP are provided. The staff carrying out RNTCP activities like LTs and DOT providers in PHIs will adopt infection control techniques as detailed in these guidelines and will take action to integrate waste generated under RNTCP into the waste management activities of the concerned PHI. The activities by the PHIs will include organized waste collection, information dissemination, reporting and monitoring of disposal of the waste.

Disposal of the General Waste

The empty blister packs, packaging material and office and kitchen waste should be considered as general waste. It does not require any treatment and will be disposed off as general waste by segregating such material in black bags. The empty vials of streptomycin after washing with water may be reused if required or disposed off with general waste of the hospital.

Disposal of sputum container with specimen and wooden sticks

Step 1: After the smears are examined, remove the lids from all the sputum cups.

Step 2: Put the sputum cups, left over specimen, lids and wooden sticks in foot operated plastic bucket/bin with 5% phenol or phenolic compound diluted to 5%. The cups and lids should be fully immersed in the solution. Keep it overnight/ for about 12 hours.

Step 3: Next day/ at the end of the day, drain off the phenol solution in to the drain.

Step 4: Take out the sputum cup/lid/wooden sticks and put into a reusable metal or autoclave-able plastic container or red bag. The red bag should have a biohazard symbol and adequate strength so that it can withstand the load of waste and be made of non-PVC plastic material.

Step 5: Put this container/bag into the autoclave with other autoclavable BMW and the contents should be autoclaved at 121°C at 15 psi pressure for 15 – 20 minutes. The autoclave shall comply with the standards stipulated in the rules. Under certain circumstances, if autoclaving is not possible, boil such waste in a pressure cooker of approximately 7 litre capacity containing adequate amount of water to submerge the contents and boiled for at least 20 minutes using any heating source, electrical or non-electrical. However the District Hospital/CHC/PHC etc. shall ultimately be expected to make the necessary arrangements to impart autoclaving treatment on regular basis.

Step 6: After adequate cooling, the material can be safely transported to a common waste treatment facility for mutilation/shredding/disposal.

If a common waste treatment facility is not available in the area, the sputum cups/lids/ wooden sticks after autoclaving, can be buried in a deep burial pit (refer page 148).

LTs and support staff handling biological waste should wear gloves (Standard/ Universal Infection Control Precautions – refer page 149).

Disposal of used Syringes/needles/broken vials

Step 1: Immediately after administering the injection, cauterize the needle on site using a suitable needle destroyer/cutter, followed by cutting of the plastic hub of the syringe without detaching the needle from the syringe.

Step 2: Put the cauterized needles, broken vials and ampoules into a sturdy puncture proof white translucent plastic/cardboard container.

Step 3: Segregate and store cut plastic syringes in a reusable metal or autoclave-able plastic container/ red bag. If a bag is used, its strength should be such that it can withstand the load of waste inside and be made of non-PVC plastic material.

Step 4: Label both the container with biohazard symbol as stipulated in the Schedule III of the Biomedical Waste (Management and Handling) Rules 1998 (refer page 153).

Step 5: Put both the containers in the prescribed bag and transport in a dedicated vehicle to the Common Waste Treatment Facility (CWTF) for autoclaving, mutilation/shredding, and/or disposal.

Step 6: If a CWTF does not exist, put both sharp container (needles) and metal / plastic container / red bag (syringes) into an autoclave with other BMW, and autoclave at 121°C at 15 psi pressure for 15–20 minutes. Under certain circumstances if autoclaving is not possible, boil such waste in water for at least 20 minutes. However the District Hospital/CHC/PHC etc. should ultimately be expected to make the necessary arrangements to autoclave the waste on regular basis.

Step 7: Dispose off the autoclaved waste as follows:

(i) Dispose off the needles and broken vials into a sharps pit; and

(ii) Send the syringes for shredding/mutilation or as a landfill in a deep burial pit.

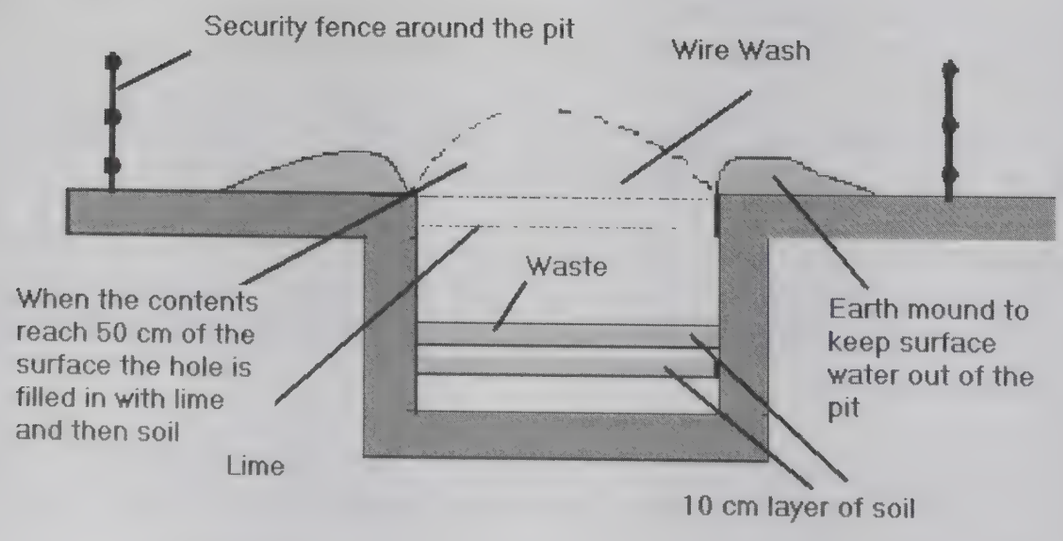
Disposal of stained slides

Step 1: The slides should be put into a puncture proof container and red bag. The red bag should have a biohazard symbol and should be made of non-PVC plastic material. This bag/sharp container should then be put in to an autoclave or pressure cooker for autoclaving/boiling.

Step 2 : Dispose off the autoclaved/ pressure boiled slides into a pit for sharps.

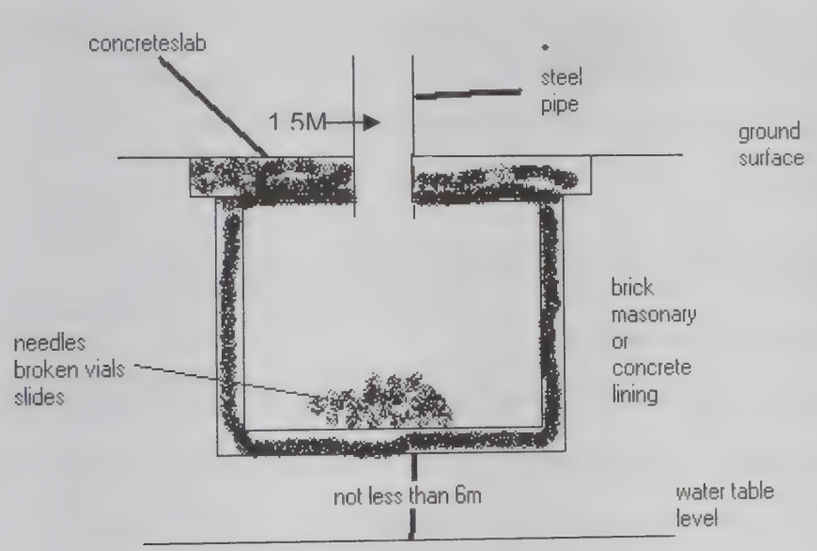
Under no circumstances should the slides should be broken.

Design for Deep Burial Pits



Pit for onsite disposal of Sharps

The treated needles/broken vials should be disposed in a circular or rectangular pit as shown in figure below. Such rectangular or circular pit can be dug and lined with brick, masonry or concrete rings. The pit should be covered with a heavy concrete slab, which is penetrated by a galvanized steel pipe projecting about 1.5 meters above the slab, with an internal diameter of up to 50mm or 1.5 times the length of vials, which ever is more. The top opening of the steel pipe shall have a provision of locking after the treated waste sharps has been disposed in. when the pit is full it can be sealed completely, after another has been prepared.



Standard (Universal) Precautions

In 1996, CDC developed a new system of standard precautions synthesizing the features of universal precautions and body substance isolation. Standard precautions are used in the care of all patients and apply to blood, all body fluids, secretions and excretions except sweat, regardless of whether they contain visible blood.

Standard precautions include:

- Hand washing;
- Barrier protection;
- Safe handling of sharp items;
- Safe handling of specimen (blood, etc.);
- Safe handling of spillage of blood/body fluid; and

- Use of disposable/sterile items.

Hand washing

This is an ideal safety precaution and gloves should not be regarded as a substitute for hand washing.

For General patient care (hand decontamination)

- Wash hands thoroughly in running water with soap without missing any area. For effective hand washing first wash palms and fingers followed by back hands, knuckles, thumbs, fingertips and wrists. Rinse and dry hand thoroughly.
- Wash hands immediately after accidental contamination with fluid, before eating and drinking and after removing gowns/coat/gloves.
- Leave soap bars in dry container to prevent contamination.

For Surgical care (surgical scrub)

- Wash hands up to the elbows.
- Scrub hands for minimum of 2 minutes.
- Prevent dripping down of water from unwashed area of arms to washed hands.
- Put on gowns and gloves after drying only.

Barrier Protection

Gloves

- Wear while collecting/handling blood specimens and blood soiled items.
- Wear while disposing of waste material.
- Remove before handling door knobs, telephone, pen, or performing office work.
- Discard if cracked, discoloured or punctured.
- Discard if blood spills on them.
- Don't reuse disposable gloves.
- Wash hands when gloves are removed or changed.

Masks

- Wear masks and protective glasses if splashing or spraying of blood/ body fluids is expected.

- Masks of cotton wool, gauze, or paper are ineffective. Only specially designed paper masks with synthetic material designed for filtering out aerosols are protective.

Caps

- Cover hair completely in aseptic units, operating rooms or performing selected invasive procedure.

Gown and aprons

- Wear clean clothes, made of a material which is easy to clean.
- Change after exposure to blood and body fluids.
- Wear gown or apron of plastic water resistant paper when splashes of blood or other body fluids are likely to occur e.g. during surgery, obstetric procedures, invasive procedures, post mortem and embalming.

Occlusive bandage

- Cover all skin defects e.g. cuts, scratches or other breaks, with a waterproof dressing before patient care.

Safe handling of sharps

- Take extra care to avoid autoinoculation.
- Discard all chipped or cracked glassware in appropriate containers.
- Never use hands to pick up broken glass. Use a brush and pan.
- Don't manipulate disposable needles. Never bend, break, recap or remove needle from syringe.
- Dispose of your own sharps. Don't pass used sharps directly from one person to another.
- Discarded needles are to be placed in puncture proof rigid containers (plastic or cardboard boxes) after disinfection in freshly made 5% phenol/ 5% sodium hypochlorite solution. Use a needle shredder if available for needles or needles along with syringe nozzle.
- Send sharp disposal containers for disposal when three-quarters full.

Safe handling of specimen

- Collect specimens, specially blood and body fluids, in pre-sterilized containers properly sealed to prevent leakage or spillage.

- Use autoclaved/pre-sterilized disposable syringes and needles for vene-puncture, and lancets/cutting needles for finger pricks.
- Cover cuts in hands properly with water proof adhesive bandages.
- Wear disposable gloves while collecting blood/body fluids and maintain proper asepsis.
- Wash hands thoroughly with soap and water, particularly after handling specimens.

Safe handling of blood/body fluids spills

- Cover spills of infected or potentially infected material on the floor with paper towel/blotting paper/newspaper.
- Pour freshly made 5% sodium hypochlorite solution on and around the spill area and cover with paper for at least 30 minutes.
- After 30 minutes, remove paper with gloved hands and discard in general waste.

Use of disposable sterile items

- Ensure proper handling of disposable/sterile item before/during use.
- There should be no re-circulation of disposable items.

LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS

BIOHAZARD

CYTOTOXIC

Handle with care

Specification for BIOMEDICAL WASTE Bags

The plastics bags should be made of :

Polypropylene or Polyethylene with 80-120 micron thickness or 200, 400, 600 gauze. These should be 'tear resistant'.

ANNEXURE VI: IMPROVING INTERPERSONAL COMMUNICATION SKILLS IN RNTCP TRAINING: KEY CONCEPTS AND SAMPLE ROLE PLAYS

INTRODUCTION

The Revised National Tuberculosis Control Programme (RNTCP) is succeeding. Currently, it covers more than 85% of India and, by 2005, entire country will be covered.

The principles of the RNTCP are:

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum microscopy (using microscopy to examine sputum smears among patients in health facilities)
- Uninterrupted supply of Good quality drugs (short-course chemotherapy, patient-wise boxes)
- Direct Observation of treatment (The right treatment, given the right way)
- Systematic monitoring and accountability (outcome of each and every case initiated on treatment).

Successful application of each of these principles depends, in part, upon developing and maintaining positive relationships among the individuals who work in the Programme, as well as with the community and patients who are served by the Programme. While technical and clinical aspects of the Programme must be adequately addressed, social and communication dimensions are equally necessary to make this information acceptable, and to encourage Programme participation. Interpersonal communication (IPC) skills are invaluable at all levels of the RNTCP, and are powerful tools to help cure patients, and thereby, to control TB.

For example, quite often patients discontinue treatment as soon as they start feeling better. They may not understand about drug-resistant TB and that it can be very difficult to cure. This sort of information needs to be conveyed to patients and their families without causing undue alarm. Service providers should be able to communicate with the patients in a way that makes patients feel comfortable and ensures that patients develop confidence in the service providers and ultimately in the services received. The best way to make a patient comfortable is to communicate in a language that is easily understood by the patient. Sympathy and concern about the patient and his/her disease should invariably emerge during the conversation. Good IPC encourages patients to complete treatment and also consult the service provider in case of any questions or concerns (such as adverse effects of the medications). Willingness to contact the

service provider to clarify any apprehensions is an important indicator of good IPC between patients and providers.

In addition to improving interactions with patients, good IPC skills will help RNTCP staff obtain participation from officials, laboratory personnel, public sector physicians, and treatment observers.

How we learn to change behaviour
People adopt habits and behaviour for a variety of reasons. Changing behaviour is often a gradual and complex process.

Information: We often become aware of the need to change behaviours by receiving information. But information alone is rarely enough to bring about the change. We often have information but are still not motivated to change our behaviour. Some reasons for this are:

- We don't believe the information
- We don't believe that we are capable of changing
- We believe that the behaviour is not under our control
- We believe that the change is not warranted.

Motivation: We often actually get started on a change as a result of a personal experience or crisis that provides us with the motivation to try a difficult change.

Support: To succeed, most of us receive some form of support. Support comes from something we find within ourselves and/or from peers, family, health workers and others who are important to us.

To help people change their behaviour, good IPC, or "counseling" skills will work toward providing information, motivating, helping people to overcome obstacles, and providing support to try to change.

Counseling is a process of enabling/helping someone to overcome a problem; meet a need, make a decision, or accept their situation. Counseling differs from education. Education involves providing information. Counseling is a process of helping others use information and relate it to their own lives. Counseling is not giving advice alone. The aim of counseling is not to solve other people's problems but to enable people to solve their own problems. Good counseling is client-centered, which means counseling must centre on the client's feelings, thoughts, concerns and needs. Thus, counseling is a process of empowering clients to make their own decisions through defining feelings and providing objective information.

Characteristics of effective counseling:

- Confidential
- Non-judgmental
- Non-directive
- Empathetic
- Encouraging
- Reinforcing

Types of Communication

There are two types of communication—verbal and non-verbal. Verbal communication is for correctly providing facts. This is important, but is only one component of communication. The other component is non-verbal communication.

Non-verbal communication creates the atmosphere of the interaction. It can create either a welcoming, caring environment that makes the facts acceptable and easy to understand, or a formal, confusing, or even hostile environment that makes it difficult for the facts to be understood or accepted.

Effective communication skills include active listening, praise and encouragement, paraphrasing (repeating in slightly different words), questioning, reflecting, and non-verbal communication. Communication is a process by which information, ideas and/or feelings are exchanged between individuals. The ability to communicate effectively can be learnt.

The development of good verbal and non-verbal communication by improving IPC skills is the focus of this module. It will help trainers and trainees to develop insights into and improve their own behaviour. Role plays are a good way to practice interacting with others and to improve IPC skills.

The skills involved in good interpersonal communication include:

- Listening and Understanding
- Demonstrating caring, concern and commitment
- Problem solving and Motivating

Listening and understanding involve more than simply being present while someone is speaking. Active listening means genuinely hearing the other person's words. Often, we think we are listening, but we actually do not pay close attention or do not really hear

what the other person is trying to say. Some key points for improving listening and understanding skills include:

DO:

- Offer a seat before interacting with the patient
- Allow sufficient time for the interaction
- If time must be limited, give your full attention during the time you have and the same should be apparent to the patient
- Be prompt so the other person does not have to wait a long time for your attention
- Sit with the other person so you are at their level
- Maintain eye contact
- Move your head to indicate you are paying attention
- Apologize for any unforeseen interruptions
- Ask open-ended questions (questions that cannot be answered with "yes" or "no") such as questions that begin with "What", "Why" or "How". These questions require more than just a few words in the answer
- Periodically summarize what the other person has said to ensure that you have understood; use their own words to repeat the ideas back to them.

DON'T:

- Interrupt while the other person is speaking
- Yell at the other person
- Ask questions that can be answered with just one word (for example, questions that begin with "Do")
- Perform other activities during the meeting
- Ask difficult/embarrassing questions

* * *

You can demonstrate that you care by expressing your understanding of the feelings and concerns of the other person and by letting them know that you want to help them. You can reflect the other person's emotions back to them with facial expressions that show you are concerned. You can also provide verbal feedback to them to show acknowledgement and recognition of their fears and concerns. Some key points are:

DO:

- Greet the patient
- Say, "Hello, please be seated."
- Address the person by name or appropriate title but always with respect
- Acknowledge and respond to each of their concerns
- Emphasize that your job is to help them
- Ask about family members
- Treat the person with respect
- Smile.

DON'T:

- Minimize or dismiss their concerns
- Put down the other person
- Act superior
- Assume the person knows their way to another person/room/office; give them proper guidance to their next destination
- Argue with the patient.

* * *

After listening, understanding and showing that you care, you can then use your knowledge of the RNTCP to discuss ways you can work together to solve any problem the other person has with participating in the Programme. Some key points for this include:

DO:

- Listen carefully to their point of view
- Paraphrase and summarize frequently to make sure that you understand the problem Use non-technical words
- Help them to comply
- Demonstrate that you are concerned about the patient
- Convey that you understand their fears and apprehensions
- Make them comfortable
- Identify obstacles to their participation

DON'T:

- Assume you know all the answers
- Use technical words
- Treat them as your student
- Tell them to comply
- Assume you know their condition
- Expect compliance without explanation.

★ ★ ★

Finally, you can use all of the knowledge, understanding and trust you've gained during your interaction to continue to motivate each person to maintain involvement in the Programme. Here are some of the main points to keep in mind for motivating:

DO:

- Repeat important information in different ways each time you meet
- Emphasize that your job is to help them
- Emphasize that they will be cured
- Use examples from your own experience
- Tell them that this is what you would recommend to your family members
- Compliment the other person on what they have done well
- Recognize their progress
- Emphasize that their welfare is your concern/job

DON'T:

- Use technical words
- Ignore the efforts the other person has made so far
- Overlook their fear and anxiety
- Ignore or minimize practical barriers
- Criticize their omissions/commissions.

★ ★ ★

HOW TO USE THIS SECTION

This section contains role play examples for RNTCP trainers. Groups should perform the role plays in the section that pertains to their defined role in RNTCP. This section must be used throughout the training to ensure that participants receive consistent information. Role plays should be performed at appropriate time in the course of training.

The section begins with a role play that should be performed by the trainer(s) to exhibit as many poor IPC skills as possible. The trainer(s) should tell the group to watch this role play looking for poor IPC behaviours. The trainer(s) will perform the scene using many of the "DON'Ts" listed earlier and performing as many incorrect IPC skills as possible. Stress these poor behaviours to the point of comedy. It must be made clear that poor IPC behaviours are NOT acceptable for good IPC.

After the performance, have the group make a list and discuss the exhibited poor IPC skills. Then, address each of these behaviours in turn, and discuss ways that good IPC skills could be substituted for the poorer ones. Finally, the trainers should perform the same role play again, using only good IPC skills. After this performance, discuss with the participants the differences between the two scenes. Also have the participants discuss how they think each person in the scene felt and the differences in their feelings between the first and second scene.

Once this discussion is finished, you will have the participants form smaller groups of no more than six people per group. Then, ask the group members to perform relevant scenes listed in this book using as many effective IPC skills as possible. Participants who play the role of patient or person being supervised should be told that they should freely add/invent details which are realistic. Groups do not need to perform ALL of the scenes listed, but continue to have them perform scenes until you feel the important points have been covered sufficiently and everyone in the group appears to be able to exhibit good IPC skills. Trainers and participants should invent more role play scenes that depict their own experiences and use these in addition to or instead of the role play scenes in this book.

Motivate the participants. If they are reluctant to do role plays because they feel they are not "actors", tell them that they do indeed act every day. Everyone does. Each time they interact with another person, they are acting. Whenever they try to convince someone to do something, they are acting. If they are tired but must appear energetic toward their boss, they are acting. When they first met their wife or husband and wanted to impress them, they put on their best behaviour. This is normal, natural behaviour and is acting.

Give them these and other examples from your own experience to help them realize they already have the skills to do the role plays.

During the role plays, observe each group but avoid interrupting them; interrupt only if the participants are having extreme difficulty or are going totally out of context.

It will be your job to answer questions, talk with the participants about the role plays, lead group discussions and generally give participants any help they need to successfully develop better IPC skills. To do this, you will need to be very familiar with the material being taught.

Ensure that each participant understands what they are expected to do in the role play exercises. By participating in the role play scenes, they will be able to:

- observe and practice the desired practical responses to patients and others
- discuss and share ideas with each other about the situations
- use what they have practised when they encounter these situations during the course of their own work.

Role plays should be used to sharpen IPC skills so that these skills will come naturally during RNTCP work.

Demonstrate good interpersonal skills yourself

Answer questions from the participants
Encourage the participants to ask questions and make comments. This means that you need to be available when participants are working on the role play. Respond positively to questions (for example, say, "Yes, I see what you mean." or "That's a good question."). Avoid facial expressions and comments that convey that the question is trivial. Always spend enough time with each participant to answer their questions fully so that both you and the participant are satisfied. If you cannot answer a question, say so. Get help from others in the group or from a colleague.

Clarify any issues that the participant finds confusing
Role plays allow you to see what participants do and do not understand. Do not always wait for a participant to ask for help. Instead, as you watch the participants, offer help during pauses or breaks, without interrupting. Help the participants understand how to solve practical problems in actual situations. Identify gaps in a participant's understanding and skills and provide help to correct them. If a participant has difficulty with the language used, make sure they receive the help needed to understand the concepts. Use language which is familiar to the participants.

Lead group discussions at the end of each role play
Ask questions to spark discussion. Use open-ended questions to get participants to share information and experience. Open-ended questions are questions that require more than a yes or no answer. When you ask a question, pause long enough to give

participants a chance to think about their answer and to respond. Allow silences so participants can have time to think before responding.

Check to see if participants are having problems, even if they do not ask for help
If you show interest and give each participant undivided attention, they will be more motivated. Also, if the participant knows that someone is interested in what they are doing, they are more likely to ask for help when they need it. Be available to the participants at all times; remain in the room and look approachable.

Answer participants' questions willingly and encourage them to ask questions when they arise rather than waiting until a later time. Call the participants by name when you talk with them. Maintain eye contact with the participants. Present information in the form of a conversation rather than by just reading it. Move around the room and use natural hand gestures. Speak clearly. Vary the pace and pitch of your voice. Paraphrase and summarize frequently to keep participants focused and clear on a particular idea and to keep discussions on track. Demonstrate enthusiasm for the work that the participants are doing. Compliment each participant for improvements in understanding, approach or progress. Get everyone in the group to share experiences so they can learn from each other. Encourage participants to explore how the role plays apply to their activities and how the IPC skills will help them in improving cure and case detection.

Manage
Make sure participants have access to supplies and materials when they need them (for example, chalk and board to write) and that there are no major obstacles to learning (such as too much noise, not enough light or not enough work space). Make the course interesting by giving examples from real work situations. Think about the skills taught in the role plays and how they can be applied to the participants' jobs. Add these to the points to be made when introducing or summarizing the role play. Discuss the application of new concepts to real problems. Ask participants whether they can use the skills that were taught, and discuss any potential difficulties in implementation of these skills. Do not summarily reject alternative methods suggested by the participants; discuss alternative methods thoughtfully and positively.

Role plays are fun and effective methods of developing good IPC skills. This will benefit all levels of the RNTCP staff to help reach the Programme's goals. The use of this section will serve to improve your own IPC skills as well as those of your colleagues.

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ROLE PLAYS FOR DOCTORS

Introduction

Example Role Play

You are a doctor talking to a newly diagnosed TB patient. The Patient does not believe he has TB. He agrees for an X-ray, but not for sputum examination

Sample Key Messages

Role Play Scenarios

1. Doctor is meeting with a patient diagnosed as having TB by a private doctor on the basis of an X-ray report. The patient wants free drugs without delay and without further examination.
2. Doctor is meeting with a newly diagnosed TB patient, a daily wage-earner and who is reluctant for direct observation because he does not want to miss work
3. Doctor is meeting with a chest symptomatic patient who is reluctant to give 3 sputum samples and is ready to bribe the doctor
4. Doctor is meeting with a newly diagnosed schoolboy who does not want to disclose his illness
5. Doctor is meeting with a newly diagnosed patient who is a truck driver and who says he will have difficulty coming to the local facility for DOTS when he is working
6. Doctor is meeting with a chest symptomatic patient from a tribal area who insists on hospitalization
7. Doctor is meeting with a newly diagnosed married woman who does not want her husband or family to know about her illness
8. Doctor is meeting with the father of a woman who is to be married and he does not want the community to know that his daughter has TB
9. Doctor is meeting with a newly diagnosed TB patient who wants to leave the area
10. Doctor is meeting with an urban, educated Category II patient who is afraid of injections because he is afraid of HIV transmission
11. Doctor is meeting with a newly diagnosed sputum-positive TB patient who is reluctant to bring in her family members for examination because she feels guilty about possibly having infected them

INTRODUCTION

For developing good interpersonal communication (IPC) skills, you, the trainer, will need to be aware of the duties that the doctors have to perform. These include explaining to the patient about TB and the importance of continuing treatment. They also include developing a strong bond with the patient to help motivate them to continue participation in the treatment. Doctors also need to be able to gain the trust of the patient's family and community. In addition, doctors must provide an example to their staff about how to interact with patients.

In this section, you will help the doctor participants become better at these duties through role plays. Through the role plays, poor IPC skills and good IPC skills will be demonstrated. Demonstrating poor IPC skills develops insight into common behaviours that occur in real situations. Identification of these will help in working towards developing good IPC skills. Therefore, for the role plays to be effective, two sessions will have to be done for each scene; one highlighting poor IPC skills and the other showing good IPC skills. In order to help the participants understand the importance and potential pitfalls of non-verbal communication, perform the following exercise: Tell the participants to just observe you without making any comments. Then, sit down in a chair with your arms and legs crossed, your body turned slightly away from the participants, and an annoyed expression on your face. Swing your legs and gaze around the room. After about 30 seconds, ask the participants to describe what they were feeling when you were sitting in front of them. List their responses on the board or flip chart.

Then discuss:

- Do we communicate without words?
- Describe ways that we communicate without words.

Discuss with them that we need to be aware of what we are communicating non-verbally, for example, boredom, dislike, superiority, impatience We also need to be aware of what our patients and others communicate non-verbally, such as fear, embarrassment, discomfort and shame.

After this discussion, you will tell the participants that you are going to enact a role play scene for them. Tell them to watch for behaviours that depict poor IPC skills.

Next, choose another trainer (if available) or a participant (if no other trainer is available) to play the part of the patient in the following role play. A trainer should play the part of the Doctor. You will then enact the following role play scene using as many poor IPC skills as possible (for example, you will yell at the patient, you will have them stand while you sit, you will tell them facts using big words that they don't understand, and so forth).

Role Play Scene

Doctor: You are a doctor talking to a newly diagnosed TB patient.

Patient: You are a patient who does not believe you have TB. You agree to have an X-ray, but do not agree to have your sputum examined.

After you have completed enacting the scene, ask the participants to list the poor IPC skills. Write these on the chalk board or flip chart. Then, go through each item listed and discuss the ways in which the poor behaviours could be improved. Spend as much time as needed to thoroughly discuss the poor behaviours. Be sure to discuss non-verbal communication elements such as eye contact, posture, nodding, encouraging or discouraging sounds, etc.

Also discuss the messages about the RNTCP that were conveyed during the scenario. Discuss the accuracy of the messages and, for inaccurate messages, discuss how they could be more accurately conveyed.

Once the discussion is finished, perform the scene again using only good IPC behaviours. Afterward, ask the participants to discuss the differences in the two role play scenes. Encourage them to discuss how the two different scenarios made them feel and how they think the patient and Doctor felt in each scene.

After this discussion, inform the participants that everyone in the group is now going to practice IPC skills by doing role plays themselves, with the other participants. Tell them that you will be handing out their roles and that they will perform the scene twice; once using poor IPC skills, followed by a group discussion on how the behaviours can be improved, and then again using good IPC skills.

Split the group of participants into smaller groups of no more than six people per group. Make sure each small group contains an even number of participants. Then, choose scenarios from the list of "Role Play Scenarios for Doctors" which can be found at the end of this chapter and write the roles on separate pieces of paper to give to the participants in each small group. You can also use your own experiences to come up with other role play scenarios and roles. Make sure that everyone receives a role.

After you have handed out the roles, give the participants a few minutes to think about how they will act out their role. Then, have the participants play each scenario in front of their small group using good IPC skills.

During the play by the trainees, circulate to each group to ensure that participants are exhibiting the appropriate IPC skills, such as smiling, sitting with the patient or other person, looking at the other person when speaking, pausing after asking questions, asking open-ended questions, etc. Also, use the following list of "Key Messages" to guide you as you watch the role play. After each role play by the participants, stop and have the group discuss the good ideas and IPC skills that were exhibited in the role play scene, and also discuss things that could improve IPC skills and improve the accuracy of RNTCP messages.

SAMPLE KEY MESSAGES

Listening and understanding

"Please sit down."

"How are you feeling?"

"How many children do you have?"

"Where do you stay? How long have you been residing in this area?"

"What are their ages?"

"How is your wife/husband?"

"Are they doing well?"

"What do you do for a living?"

"Tell me when you first fell sick. Since becoming ill what you have done to feel better?"

"Have you ever been ill like this before?"

"Have you ever had to take injections for over two weeks?"

"Have you ever had to take pills for many months?"

"Do you have a cough?"

"For how long have you been having a cough?"

"Is the cough dry or associated with expectoration?"

"Do you have any fever?"

"What colour is the expectoration? Is it ever blood-stained?"

"Do you get a pain in the chest when you cough?"

"How is your appetite?"

"Have you noticed any weight loss, lethargy or weakness?"

"What other symptoms do you have?"

"What medicines are you taking?"

"What medicines have you taken in the past?"

"Have you ever taken a medicine that turned your urine orange-red?"

"Has anyone in your family had an illness like this before?"

"Does anyone in your family also have cough?"

"Have you heard of TB?"

"What do you understand TB to be?"

"What do you think causes TB?"

"Have you ever seen an X-ray?"

"What do you think X-ray shows?"

"Have you heard of the microscope sputum test to diagnose TB?"

"Have you ever had a blood or sputum test?"

"Do you know that we need to test your sputum three times to confirm whether you have TB?"

"Do you know that TB can be cured?"

"Do you know that TB can spread from one person to another if it is not properly cured?"

"Do you know that other people in your house can contract TB from you?"

"Do you know that till complete investigations are done we cannot assess the degree of damage that has been caused?"

"The tests to detect TB are simple and will have to be done at regular intervals to monitor improvement in your condition."

"You will have to take your medicines as prescribed so that your illness does not get worse."

"If you do not take medicines as prescribed, you can develop a more dangerous form of TB and you will spread the same to your family."

"Covering your mouth when you cough can prevent the spread of TB to others."

Demonstrating caring

"TB is not a disease which should cause worry as it is curable if drugs are taken regularly."

"We want to make sure that you are completely cured."

"By following the treatment schedule you will also make sure that you do not spread the disease to your near and dear ones."

"All treatment is free here, so please don't even think about money."

"Anti-TB medicines are strong drugs that must be taken under direct observation. This will ensure that you not only take the medicines regularly but also in the right dosage. This way I can know that you are responding well to treatment and if you have any problems."

"Anti-TB drugs can have side-effects in some people. If you take them under our supervision, we will make sure you do not have any uncomfortable side-effects and if you do we will be able to tackle them at the earliest and prevent any problems."

"At times people develop resistance to certain drugs and show no improvement when taken irregularly. If you take the medicines under our supervision, we will be able to observe that the drugs are having the required effect and you will continue to constantly getting better."

"If you have any doubts regarding the duration of treatment, the dosages of the drugs or any side-effects, please feel free to clarify your doubts with me."

"To make sure that I have explained things well, please show me on this calendar [show the patient a calendar] how long you must take medicines."

"I want to make sure that I give you the best medicines. That is why a sputum test is so important—so we can be sure that you are getting the right medicines."

"We don't want to unnecessarily give you a strong medicine, which is why all the tests are important. The tests will tell us how severe your condition is and we can give you the best medicines."

"If you have any doubts about the disease or the medicines, do not hesitate to ask me."

"It is my responsibility to cure you."

"I am not only worried about you, but if you have TB and are not treated then your family may get sick, and obviously I do not want that to happen and I am sure you also don't want that to happen."

Motivating and Problem solving

"An ordinary cough does not last that long. You have been coughing for a month and we must find out why. Only when we know the cause can we cure it completely."

"A sputum test is very important in diagnosing the type of TB. Only then can we be sure that you are getting the right medicines for the right duration of time."

"TB is a disease and should not be a cause for worry as it is fully curable now but it should be diagnosed early so that it doesn't spread to other parts of the body or to others. Therefore, it is necessary to have your sputum tested."

"A chest X-ray will only tell us that you MAY HAVE TB. X-rays are just shadows and, like any shadow, can be caused by many different things. X-ray is not a 'pucca' test for TB."

"Sputum examinations do not cause any harm or discomfort. You just have to have 3 sputum examinations done as all treatment will be based on their results."

"If you have any doubts regarding sputum examination or want to know how to bring out sputum, you can either ask me or the laboratory technician. We will be happy to clarify your doubts and help you."

"If the sputum test confirms your disease you will get regular attention and treatment."

"A sputum test is very important for us to know what medicines should be given to you. We will start treatment as soon as we get the results of sputum examination."

"If I or my wife/husband had your symptoms, I would certainly have 3 sputum examinations done."

"The reason for conducting 3 sputum examinations is because one or two tests may not be enough to detect the TB germs."

"It is important to understand that the better the diagnosis, the better will be the treatment and faster the cure. And for a good diagnosis you must go through all the tests as prescribed. The test results will help us prescribe the best drugs for you."

"Yes, as soon as your sputum test results are available, we will also tell you whether you need to bring your family members for examination."

"Yes, your symptoms suggest that you MAY HAVE TB, but we cannot be sure till we test your sputum."

"Sputum tests are done free here, and of excellent quality. The test here is better than what you can get even in a private laboratory."

"The sputum test is much more accurate than an X-ray. We can actually see whether you have TB germs when we look at your sputum with a microscope."

"It is not just you but everyone like you who has a cough for 3 weeks or more has to go through all the tests, so that we can know exactly what the problem is and treat you accordingly."

"If it is convenient for you to come for your sputum tests on your off days, we could make adjustments for you accordingly. However, you must come for your tests on the appointed day without fail."

"To check your progress towards cure we shall again examine your sputum after two months."

"Tuberculosis is fully curable if complete treatment is given under DOTS."

"It is very important that the disease does not spread to anyone else, especially to your family members."

"After only a few days on the medication, you will stop infecting others, but you will have to continue on your medication for the full duration of 6/9 months."

"We will arrange for medicines to be provided near your home."

"I can understand that it is difficult for you to come thrice a week. We will find a treatment observer near your place of work." Or "We will arrange for the treatment observer to give you medicines before you go for work."

"If I had TB, I would certainly come thrice a week for treatment for the first two months and hence you will also be required to come."

"I understand that you do not want others to know that you have TB. We will be careful about that. But it is equally important that others do not get TB from you. If you do not take your medicines as advised, you will spread TB to others at home and work."

"Although TB is curable, cure can only take place through constant monitoring. This helps us to assess your response to the drugs. We have to make sure that there is continuous improvement and no untoward effects of medicines and that is why you are required to come on alternate days thrice a week for the first two months."

"TB can be cured completely only if treatment is uninterrupted. And the only way to ensure regular treatment is to monitor it."

"Every dose is crucial and the treatment is designed for your complete cure."

"It is not in your interest to take medicines home. Medicines can be lost. It is also easy to forget to take medicines every day."

"If you forget to take even a few doses of medicine, you may fall ill again, in which case the dosage and duration of treatment may increase and would be very expensive and your chances of getting fully cured will be reduced."

"If you come in thrice a week, we can make sure you are getting better and we can observe if you are having any problems with the medicines."

"Once you are cured you will be able to work much better and earn more. So it is in your interest to complete the entire course and come for regular check-ups as prescribed. These are all aimed at curing you completely."

"You don't want your wife and children to get tuberculosis from you. So for their sake you should get well and for that you must take the prescribed treatment regularly and completely."

"If any of them have symptoms of the disease, they also need to be examined and treated."

"If your children are infected, they will be physically weak and may not be able to help out with the household chores or in the fields. More money will be spent on medications. So it is better that you get yourself fully treated so that the question of their getting infected does not arise and they enjoy good health."

ROLE PLAY SCENARIOS

(These are only some examples. Use your own experiences to come up with other scenarios and roles.)

Scenario 1: Doctor is meeting with a patient diagnosed as having TB by a private doctor on the basis of an X-ray report. The patient wants free drugs without delay and without further examination

Write the following instructions on two separate pieces of paper and hand them out to two participants.

Doctor: You are a doctor who is seeing a patient diagnosed as having TB by a private doctor on the basis of an X-ray report.

Patient: You are a newly diagnosed TB patient who wants free drugs without further examination.

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Scenario 2: Doctor is meeting with a newly diagnosed TB patient, a daily wage-earner who is reluctant for direct observation because he does not want to miss work

Doctor: You are a doctor who is seeing a newly diagnosed TB patient in your office.

Patient: You are a TB patient who is a daily wage-earner and you do not want to come for direct observation because you do not want to miss work.

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Scenario 3: Doctor is meeting with a chest symptomatic patient who is reluctant to give 3 sputum samples and is ready to bribe the doctor

Doctor: You are a doctor who is seeing a new patient in your office.

Patient: You are a person who has had a cough for several weeks with blood in your sputum and you have come to see the doctor. You do not want to give three samples of sputum and you are ready to bribe the doctor to just give you medicines without the sputum samples.

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Scenario 4: Doctor is meeting with a newly diagnosed schoolboy who does not want to disclose his illness

Doctor: You are a doctor seeing a schoolboy who has been newly diagnosed with TB.

Patient: You are a schoolboy who has been told you have TB and you do not want to disclose your illness to your family or your friends.

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Scenario 5: Doctor is meeting with a newly diagnosed patient who is a truck driver and who says he will have difficulty coming to the local facility for DOTS when he is working

Doctor: You are meeting with a newly diagnosed patient in your office.

Patient: You are a truck driver and it is difficult for you to come to the local DOTS facility when you are working.

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Scenario 6: Doctor is meeting with a chest symptomatic patient from a tribal area who insists on hospitalization

Doctor: You are meeting with a new patient in your office.

Patient: You are a woman who has had symptoms of TB for several weeks and you want to be hospitalized until you feel better.

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Scenario 7: Doctor is meeting with a newly diagnosed married woman who does not want her husband or family to know about her illness

Doctor: You are a doctor meeting in your office with a woman who is a newly diagnosed TB patient.

Patient: You are a married woman who has been newly diagnosed with TB and you do not want your husband or family to know about your illness.

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Scenario 8: Doctor is meeting with the father of a woman who is to be married and he does not want the community to know that his daughter has TB

Doctor: You are a doctor meeting with a man who is not one of your patients but wants to talk with you.

Father of TB Patient: You are the father of a woman who is being treated for TB and you do not want the community to know that your daughter has TB.

Scenario 9: Doctor is meeting with a newly diagnosed TB patient who wants to leave the area

Doctor: You are a doctor meeting in your office with a TB patient.

Patient: You are a newly diagnosed TB patient who wants to leave the area.

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Scenario 10: Doctor is meeting with an urban, educated, Category II patient who is afraid of injections because he is afraid of HIV transmission

Doctor: You are a doctor meeting in your office with a Category II patient who is to start re-treatment.

Patient: You are an urban, educated, Category II patient who is afraid of injections because you know that needles are one of the effective means of HIV transmission.

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Scenario 11: Doctor is meeting with a newly diagnosed sputum-positive TB patient who is reluctant to bring in her family members for examination because she feels guilty about possibly having infected them

Doctor: You are a doctor meeting in your office with a newly diagnosed sputum-positive TB patient and you would like her to bring in her family members for examination.

Patient: You are a newly diagnosed sputum-positive TB patient who is reluctant to bring in your family members for examination because you feel guilty about possibly having infected them.

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REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Treatment Card

State _____ City / District with code _____

Name _____

Sex M ☐ F ☐ Age _____ Occupation _____

Complete Address _____

_____

Name and Address of Contact Person _____

_____

Initial home visit by _____ Date _____

Name of TB Unit with Code _____

Patient TB No / Year: _____

PHI: _____

Name and designation of DOT provider _____

DOT center _____

Signature of MO with date _____

Disease Classification	Type of patient	
☐ Pulmonary	☐ New	☐ Relapse
☐ Extra Pulmonary	☐ Transfer in	☐ Failure
site _____	☐ Treatment after default	☐ Other(Specify) _____

H/o previous Anti-TB treatment with duration _____

Month	Date	DMC	Lab No.	Smear Result	Weight
Pretreatment					
End IP/Extended IP					
2 Months CP					
End treatment					

I. INTENSIVE PHASE - Prescribed regimen and dosages:

Tick (✓) the appropriate Category below

Category I ☐

New Case
(Pulmonary Smear-Positive, Seriously ill Smear Negative, or Seriously ill extra pulmonary)

3 times / week

H	R	Z	E	

Category II ☐

Retreatment, (relapses, failure, treatment after default, others)

3 times / week

H	R	Z	E	S	

Category III ☐

New Case
(Pulmonary Smear Negative, not seriously ill: or extra pulmonary, not seriously ill)

3 times / week

H	R	Z	

Tick (✓) appropriate date when the drugs have been swallowed under direct observation

Month / Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

II Continuation Phase

Prescribed regimen and Dosages

Category I ☐
3 times / week

☐☐
H R

Category II ☐
3 times / week

☐☐☐
H R E

Category III ☐
3 times / week

☐☐
H R

Enter X on date when the first dose of drugs has been swallowed under direct observation and draw a horizontal line (x_____) to indicate the period during which medicines will be self administrated.

Month / Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Treatment out come with date _____ *Signature of MO with date* _____

Details of X ray / EP tests

Contacts (Children < 6 yrs)

No	Chemoprophylaxis

Remarks _____

Retrieval actions for missed doses

Date and time	By whom	Whom contacted	Reason for missed doses	Outcome of retrieval

Revised National Tuberculosis Control Programme

Transfer Form

(Fill in triplicate with carbon paper between the sheets. Send one copy to the TB Unit where the patient is transferred. Give one copy to the patient and retain one copy for the records.)

A copy of treatment card may be included along with transfer form given to patient

Name and Address of the transferring Unit (District/TB Unit): _____

Name of Unit (District/TB Unit) to which patient is transferred (if known): _____

Name of the Patient: _____ **Sex: M ☐ F ☐ Age:** _____

TB No: _____ **Date of starting treatment** _____

Disease Classification	**Type of Patient**	**Category of Treatment**	**Most Recent Sputum Status**
❑ Pulmonary ❑ Extra-Pulmonary Site_____	❑ New ❑ Relapse ❑ TAD ❑ Failure ❑ Transfer in ❑ Other(Specify)___	❑ Category I ❑ Category II ❑ Category III	**Date:** **DMC:** **Lab NO:** ❑ Positive ❑ Negative

Number of doses administered before transfer: IP _____ CP_____

Remarks:_____

_____Signature_____

Date transferred _____ Designation:_____

----------✂----------

For use by the receiving District/TB Unit **Date of outcome**_____

Name of patent_____

Old TB No (given at transferring TB Unit): _____ New TB No (given at receiving unit)_____

Treatment outcome Cured Treatment Completed Died

Failure Defaulted Transferred Out

Date _____ Signature _____

(at the end of treatment send this form to the transferring District/TB Unit where the patient was initially registered.)

(a copy of treatment card after completion of treatment may be sent to the PHI of transferring z)

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For use by the receiving District/TB Unit in case the patient was received during IP

Name of patient:_____

Old TB No (given at transferring TB unit) : _____ New TB No (given at receiving unit):_____

Sputum Results at the end of IP : Positive Grade _____ Negative

Date _____ Signature _____

(at the end of Intensive phase this form has to be sent to the transferring District/TB Unit where the patient was initially registered.)

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Name of patient _____

Old TB No (given at Transferring TB unit)_____ New TB No (given at receiving Unit)_____

Age: _____Sex: M F Date of Transfer_____

Name of TB Unit _____ District _____

The above –named reported at the TB unit on: _____

Signature _____ Designation _____ Date_____

(Send this part back to the transferring District/TB Unit as soon as the patient has reported and has been registered in the receiving TB Unit.)

TUBERCULOSIS IDENTITY CARD

Front

Revised National Tuberculosis Control Programme

IDENTITY CARD

Name of Patient: _____

Complete address: _____

_____

TU / district name _____

_____ Ph_____

____

Sex: M ☐ F ☐ Age:_____ **TB No.**_____

PHI:

Disease Classification

☐ Pulmonary

☐ Extra-pulmonary

Site:_____

Treatment Started on

Date Month Year

Type of Patient

- New
- Relapse
- Treatment after default
- Failure
- Transfer In
- Other-Specify _____

Category of Treatment

☐ Category I

☐ Category II

☐ Category III

Back

Follow up sputum examination

Time point	Date	Lab No.	Result
Pretreatment			
End of IP/extended IP			
2 months in CP			
End of treatment			

Appointment dates

IP	CP
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Treatment outcome with date:

Signature and stamp of MO with date:____

REMEMBER

1. Keep your card safely
2. You can be cured if you take treatment as advised.
3. You may infect your near and dear if you do not take your medicines as advised

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Monthly Report on Programme Management, Logistics and Microscopy

Peripheral Health Institution Level

Note: All PHCs/ CHCs/ referral hospitals/ major hospitals/ specialty clinics/ TB hospitals/ Medical colleges to submit their monthly reports in this format.

Name of Peripheral Health Institution: _____

TU: _____ **District:** _____

Month: _____ **Year:** _____

Medications

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Patients initiated on treatment (c)	Stock on last day of month (d) =a+b-c	Quantity Requested (e)= (c X 2) – d
Category I	Boxes					
Category II	Boxes					
Category III	Boxes					

Item	Unit of Measurement	Stock on first day of month	Stock received during month	Consumption during month	Stock on last day of month	Quantity Requested
Pouches of blister strips for prolongation of intensive phase	Pouches each with 12 blister strips					
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Streptomycin 0.75 g	Vials					
Rifampicin 150 mg	Capsules					
Pyrazinamide 500 mg	Tablets					
Ethambutol 800 mg	Tablets					

Staff Position and Training

Category of staff	Sanctioned	In place	Trained in RNTCP
Medical Officer			
Laboratory Technician			
Pharmacist			
MPH Supervisors			
Multipurpose Health workers			
TBHV			
STLS*			

** STLS to be reported by medical colleges only*

Referral Activities (To be filled in by all PHIs from OPD Register)

a	Number of new adult outpatient visits	
b	Out of (a), number of chest symptomatic patients referred for sputum examination	

Microscopy Activities (To be filled in by only PHIs which are a DMC from Laboratory Register)

c.	Number of TB suspects whose sputum was examined for diagnosis	
d.	Out of (c), number of sputum smear-positive patients diagnosed	
e.	Number of TB suspects subjected to repeat sputum examination for diagnosis	
f.	Out of (e), number of sputum smear-positive patients diagnosed	
g.	Total number of sputum smear-positive patients diagnosed (d + f)	

Treatment Initiation (To be filled in by only PHIs which are a DMC from Laboratory Register and Referral for Treatment Register)

h.	Of the smear-positive patients diagnosed (g), number put on DOTS	
i.	Of the number of smear-positive patients diagnosed (g), number put on RNTCP Non-DOTS	
J	Of the smear-positive patients diagnosed (g), the number referred for treatment to other TUs within the district	
k.	Of the smear-positive patients diagnosed (g), the number referred for treatment outside the district	

Consumables (To be filled in by only PHIs which are a DMC)

Item	Unit of Measurement	Stock on first day of Month	Stock received during Month	Consumption during Month	Stock on last day of Month	Quantity requested
Sputum containers*	Nos.					
Slides	Nos.					
Carbol Fuchsin	Litres					
Methylene Blue	Litres					
Sulphuric Acid	Litres					
Phenol/hypochlorite	Litres					
Immersion Oil	mL					
Methylated Spirit	Litres					

*** PHIs that are not a DMC, but have been supplied with sputum containers should complete this row.**

Equipment in place (To be filled in by only PHIs which are a DMC)

Item	Number in place	In working condition	Not in working condition
Binocular microscopes			
Monocular microscopes			

Name of officer reporting (in Capital Letters) :

Signature : _____

Date : _____

Form A **Serial Number**

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral for treatment form

(Fill in triplicate. send one to the respective DTO receiving the patient [Form A], send one copy to the health facility where the patient is referred to [Form B], and give one copy to the patient

Name and address of referring health facility_____

_____

Name of health facility to which patient is referred _____

_____

Name of patient_____ **Age**_____ **Sex M F**

Complete Address_____

Type of patient

New ☐ Relapse ☐

Failure ☐ Treatment after default ☐

Other (specify)_____

Category of Treatment

☐ Category I

☐ Category II

☐ Category III

Disease Classification

☐ Pulmonary

☐ Extra-Pulmonary

☐ Site_____

Sputum Status

Date **Month** **Year**

Result

Laboratory number

Name of Laboratory

Relevant examination for smear-negative/Extra pulmonary cases

Remarks

Signature

Date referred **Designation**

Form A

Serial Number_____

For use by the health facility where the patient has been referred

Name of patient _____ TB No (if available)_____

Age _____ Sex M ☐ F ☐ Date of referral _____

Name of receiving health facility_____ Name of TB Unit and District____

The above-named reported at this facility on _____and has been put on treatment on

Signature_____ Designation_____

Date_____

(Send this part back to the referring unit as soon as the patient has reported has been initiated on RNTCP treatment.)

FORMAT OF REFERRAL FOR TREATMENT REGISTER

S NO	Date of referral	Name	Age	Sex	Complete Address[1]	Lab Serial No	Date of sputum exam[2]	Sputum results[2]	Diagnosis			Referred to PHI/TU/District (Name)	Date of feedback from receiving health facility/Date of starting treatment[3]
									P/EP	Type of patient (N/R/F/ TAD/O)	Cat (I/II/III)		

1 *Complete address of the patient where he/she will be residing during the course of treatment and where he/she can be contacted.*

2 *if a extra-pulmonary TB patient, it should be written whether the patient was diagnosed on clinical examination alone or by additional technique which should be specified.*

3 *The date when the feedback is received by the referring health facility from the receiving health facility that the patient has been received by that unit, should be written here. Also the date that the patient started on treatment should be written here. In addition, if available the patient's TB number should be written in here.*

***Note**: For patients referred within a district, if no feedback has been received by the referring health facility from receiving health facility within 14 days of the referral date, the STS responsible for the referring health facility should be informed. They should then subsequently take up the matter with the STS of the receiving health facility during the regular meetings of the STS of the respective district.*